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Electroacupuncture for stress-related urinary incontinence in elderly women: data analysis from two randomised controlled studies

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ABSTRACT

Objective To compare the efficacy of electroacupuncture (EA) in elderly and non-elderly women with stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (MUI).

Methods This study was a secondary analysis of two randomised controlled trials involving 252 women with SUI and 132 women with stress-predominant MUI who were treated with the same EA regimen. Elderly women were defined as those aged >60 years. The main outcome measure was the proportion of patients with ≥50% decrease in the mean 72-hour urinary incontinence episode frequency (IEF) from baseline to week 6. Overall, 1004 women were recruited in the SUI and MUI trials. In the EA group, those with urge-predominant or balanced MUI at baseline were excluded from the current study, resulting in a sample size of 384.

Results Out of 384 patients with SUI or stress-predominant MUI who were treated with EA, 371 completed the study. After 6-week treatment, the proportion of women who achieved ≥50% decrease in mean 72-hour IEF from baseline was 57.3% (51/89) in the elderly group and 60.70% (173/285) in the non-elderly group; the between-group difference was not significant (3.11%, 95% CI −9.83% to 16.05%; p=0.637). Similar outcomes were observed at weeks 4, 16 and 28. Both groups showed reduction in the 72-hour IEF, amount of urine leakage (assessed by 1-hour pad test) and International Consultation on Incontinence Questionnaire-Short Form score from baseline with no significant between-group difference. No obvious EA-related adverse events were observed during the study.

Conclusion EA may be an effective and safe alternative treatment for SUI or stress-predominant MUI in both elderly and non-elderly women. Age may not affect the treatment outcomes of acupuncture.

Trial registration numer NCT01784172, NCT02047032.

INTRODUCTION

Urinary incontinence, the involuntary loss of urine, is a common complaint in women. Stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence (MUI) is characterised by involuntary leakage of urine from the urethra on physical exertion, sneezing or coughing.[1] The reported prevalence of SUI or stress-predominant MUI ranges is from 4% to 36%.[2 3] The main pathophysiological mechanisms and treatment modalities for stress-predominant MUI are similar to those of SUI, which provides the rationale for considering these two diseases collectively.[4 5] The physical and psychological damages of patient with these clinical characteristics adversely affect the daily life of the afflicted individual; in addition, women with SUI or stress-predominant MUI are more likely than men to have a poor quality of life.[6]

Most evidence-based guidelines recommend behavioural interventions as the first-line approach for treatment of patients with SUI or stress-predominant MUI; however, these require long-term patient compliance and are difficult to perform.[7 8] Midurethral sling implantation is considered as the gold standard for treatment of patients with SUI characteristics, but postoperative pain and the risk of organ injury are some of the disadvantages of this approach.[9] There is a need to develop effective and safe non-surgical therapies for these conditions. The incidence rate of significant incontinence has been shown to increase with age.[10] Guidelines suggest older people with urinary

incontinence deserve special consideration,[11] because all types of urinary incontinence become common with age and coexist with other diseases. Studies showed that age might be related to the efficacy of these interventions. The efficacy of the elderly with SUI may be similar or poorer than the non-elderly, however, the evidence was of low quality.[12 13]

Available data suggest that acupuncture may have good effects for SUI or stress-predominant MUI. In 2017, we reported a randomised clinical trial of electroacupuncture (EA) for treatment of SUI; in 2019, we reported a randomised non-inferiority trial of EA in women with MUI, including 132 stress-predominant MUI patients.[14 15] The two trials have already demonstrated the efficacy of EA in women with SUI or stress-predominant MUI, but the influence of patients' age on the efficacy of EA remains unknown.

In consideration of the identical EA regimen in the two trials, we combined the participants in the SUI trial and stress-predominant participants in the MUI trial. The objective of this secondary analysis was to assess the effect of EA in elderly versus non-elderly women with SUI or stress-predominant MUI.

METHODS

This was a secondary post hoc analysis of two randomised clinical trials. A total of 1004 women were recruited in the SUI and MUI trials. In both the trials, participants were randomly assigned to receive EA or other treatment in a 1:1 ratio via a central randomisation system for clinical research. The participants, outcome assessors and statisticians were blinded to group allocation. The research protocols were developed and executed in accordance with the principles of the Declaration of Helsinki and were approved by institutional review board at each participating centre (see online supplementary appendix 1). The rationale and design of the two trials have been published in the respective protocols; all participants provided written informed consent prior to randomisation. Briefly, we summarise the two trials below.

The SUI trial was a multicentre, randomised, sham EA controlled trial that tested the effect of EA on urinary leakage among women with SUI. The study enrolled 504 participants at 12 Chinese hospitals between 8 October 2013 and 15 May 2015. All recruited participants were Chinese women (age: 40–75 years) with SUI who had incontinence pad weight gain >1 g in the 1-hour pad test. In the EA group, 252 participants received 18 sessions of EA (30 min per session, 3 sessions per week) over six consecutive weeks involving the lumbosacral region at bilateral Zhongliao (BL33) and Huiyang (BL35) with a continuous wave of 50 Hz and a current intensity of 1–5 mA for 30 min. Follow-up was conducted for 24 weeks after the treatment; 482 participants completed the study.

The MUI trial was conducted from 1 March 2014 to 10 October 2016. It was a randomised non-inferiority trial that assessed the effect of EA versus PFMT plus solifenacin therapy in women with MUI. Five hundred women (age range: 35–75 years) with MUI since at least 3 months were recruited; 132 stress-predominant MUI participants in the EA group received the same EA regimen as that in the SUI trial over 12 weeks with a follow-up period of 24 weeks. The observation time points and measurements in the two original trials are presented in online supplementary appendix 2.1.

We combined the EA group of the two trials in this secondary analysis. Those with urge-predominant or balanced MUI at baseline were excluded from the current study. This resulted in a sample size of 384 women. These included 92 elderly women and 292 non-elderly women as defined by WHO criteria for elderly in the Asia-Pacific region, that is, age >60 years.[16]

OUTCOME MEASURES

The main outcome was defined as the proportion of participants with ≥50% decrease in the mean 72-hour incontinence episode frequency(IEF) from baseline at week 6. Other measurements were: proportion of participants with ≥50% reduction in 72-hour IEF at weeks 4, 16 and 28; the mean change in 72-hour IEF from baseline at weeks 2, 4, 6, 8, 10, 12, 15, 16, 17, 18, 20, 24, 27, 28, 29, 30, 32 and 36; the mean change in the amount of urine leakage (AUL), as measured by the 1-hour pad test, at weeks 2, 4, 6 and 12; and the mean change in score on the validated Chinese version of the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at weeks 4, 6, 8, 12, 16, 18, 20, 24, 28, 30, 32 and 36. The observation measurements and different observation time points including treatment and follow-up periods are detailed in online supplementary appendix 2.1. All adverse events were documented throughout the trials.

The 1-hour pad test was performed as recommended by the International Continence Society.[1] Briefly, participants were instructed to wear a preweighed pad and drink 500 mL water in 15 min. Subsequently, they were asked to perform several strenuous activities including going up and down 24 steps, standing and sitting 10 times, coughing and running. After completing the activities, the pad was reweighed to measure the amount of urinary leakage.

A 72-hour IEF was measured using the 72-hour bladder diary. Participants were instructed to record the time and frequency of urinary incontinence, the type and volume of liquid intake, and the activities that triggered the leakage.[17]

ICIQ-SF scores range from 0 (best outcomes) to 21 (worst outcomes) with 2.52 as the minimal clinically important difference. A Chinese version of ICIQ-SF was used in the study to measure the influence of urinary incontinence on the quality of life.[18]

It contained three items pertaining to the frequency, amount of leakage and overall impact on the quality of life; a fourth non-scored item was used to assess the type of incontinence.

STATISTICAL ANALYSIS

Descriptive statistics were used for demographics, baseline characteristics and safety variables. The primary efficacy variable in the intention-to-treat (ITT) population was analysed using a generalised linear model with a binomial distribution, adjusted for imbalances in baseline variables (ie, educational level, menopause, coexisting diseases, duration and 72-hour IEF). The same analyses were used to analyse the ≥50% reduction in 72-hour IEF from baseline at weeks 4, 6, 16 and 28. The general linear model, with treatment and unequally distributed baseline variables as covariates, was used for continuous outcomes (ie, 72-hour IEF, ICIQ-SF score and 1-hour AUL). Safety data were provided for descriptive purposes only. Any missing data were not imputed. All statistical tests were two sided, and p values less than 0.05 were considered indicative of statistically significant difference.

RESULTS

A total of 384 participants were enrolled in the secondary analysis and 371 participants completed the study (3 dropped out in the elderly group and 10 in the non-elderly group). There were 92 (24.0%) women in the elderly group and 292 (76.0%) in the non-elderly group. The mean age was 66.3 years old in the elderly (SD 3.8) and 50.6 years old in the non-elderly (SD 6.2). Out of 384 participants, 252 were menopausal. The mean BMI in the study population was 24.9 kg/m^2. The mean duration of SUI was 6.9 years. Baseline characteristics were similar between groups except for SUI duration, 72-hour IEF, menopausal status and educational level. These factors were adjusted for in the statistical analysis. The baseline characteristics of participants in the two groups are summarised in table 1.

The proportion of patients with ≥50% reduction in mean 72-hour IEF from baseline at week 6 was 57.3% (51/89) in the elderly group and 60.7% (173/285) in the non-elderly group; the between-group difference of 3.11% (95% CI −9.83% to 16.05%; p=0.637) was not statistically significant. Similar results were obtained with respect to the proportion of patient with ≥50% reduction in mean 72-hour IEF from baseline at weeks 4, 16 and 28 (p>0.05 for all). According to the subgroup analysis of the SUI and MUI trials, no significant between-group differences were observed at weeks 4, 6, 16 and 28 (p>0.05 for all, except p=0.043 of MUI trial at week 28). Table 2 shows the detailed results of the proportion of patients with ≥50% reduction in mean 72-hour IEF and the subgroup analysis.

The trends of change from baseline in the results of 72-hour IEF, AUL and ICIQ-SF score are shown in figure 1A–C. As can be seen from the dotted-line chart, all parameters exhibited a consistent downward

Table 1 Baseline patient characteristics

	Elderly (n=92)	Non-elderly (n=292)	Total	P value*
Age, mean (SD)	66.3 (3.79)	50.6 (6.24)	54.4 (8.84)	<0.001
BMI, mean (SD)†	25.3 (4.11)	24.7 (5.11)	24.9 (4.85)	0.577
Race, no (%)				0.708
Han	89 (96.7)	285 (97.6)	374 (97.4)	
Minority	3 (3.3)	7 (2.4)	10 (2.6)	
Educational level, no (%)				0.004
Primary education or below	33 (35.9)	119 (40.8)	152 (39.6)	
Secondary education	48 (52.2)	164 (56.2)	212 (55.2)	
Tertiary education	11 (12.0)	9 (3.1)	20 (5.2)	
Childbearing, no (%)	92 (100.0)	290 (99.3)	382 (99.5)	>0.999
Menopause, no (%)	89 (96.7)	163 (55.8)	252 (65.6)	<0.001
Coexisting diseases, no (%)‡	21 (22.8)	33 (11.3)	54 (14.1)	0.006
Duration, mean (SD) years	9.4 (8.44)	6.1 (6.11)	6.9 (6.87)	<0.001
72-hour IEF (mean)	11.6 (11.41)	8.0 (8.10)	8.8 (9.11)	<0.001
1 hour AUL (mean)	20.6 (26.98)	17.6 (22.76)	18.3 (23.84)	0.286
ICIQ-SF score (mean)§	11.4 (3.63)	10.6 (3.21)	10.8 (3.33)	0.052

*All tests were two sided. P<0.05 was considered significant.

†Calculated as weight in kilograms divided by height in metres squared.

‡Coexisting diseases include disease have no affect outcome measurements and confirm to inclusion criteria.

§ICIQ-SF scoring was additive (0–21), with higher scores indicating worse outcomes.

AUL, the amount of urine;BMI, body mass index; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; IEF, incontinence episode frequency.

Table 2 Proportion of patients having a 50% or greater reduction in 72-hour IEF compared with baseline at each interview point by study*

	Week 6 (main outcome)	Week 4	Week 16	Week 28
Combined trial				
Elderly (n=92)	51/89 (57.30)	32/90 (35.56)	61/89 (68.54)	65/89 (73.03)
Non-elderly (n=292)	173/285 (60.70)	123/286 (43.01)	191/282 (67.73)	198/282 (70.21)
Difference	3.11 (−9.83 to 16.05)	4.04 (−8.52 to 16.61)	−1.65 (−13.92 to 10.63)	−3.06 (−14.64 to 8.52)
P value	0.637	0.528	0.793	0.604
SUI trial				
Elderly (n=56)	38/54 (70.37)	23/54 (42.59)	39/54 (72.22)	42/54 (77.78)
Non-elderly (n=196)	124/192 (64.58)	86/192 (44.79)	118/189 (62.43)	123/189 (65.08)
Difference	−5.90 (−21.52 to 9.72)	−0.90 (−17.04 to 15.24)	−7.58 (−23.80 to 8.35)	−13.09 (−27.22 to 1.04)
P value	0.459	0.913	0.351	0.07
MUI trial				
Elderly (n=36)	13/35 (37.14)	9/36 (25.00)	22/35 (62.86)	23/35 (65.71)
Non-elderly (n=96)	49/93 (52.69)	37/94 (39.36)	73/93 (78.49)	75/93 (80.65)
Difference	15.70 (−5.71 to 37.11)	10.30 (−10.08 to 30.68)	18.14 (−1.20 to 37.49)	18.94 (0.57 to 37.30)
P value	0.151	0.322	0.066	0.043

*Data are described as number/total number of patients (%), unless otherwise indicated.
IEF, incontinence episode frequency; MUI, mixed urinary incontinence; SUI, stress urinary incontinence.

trend over time. At week 6, the mean change in the 72-hour IEF from baseline in the elderly group was −4.1 (95% CI −5.2 to −3.1), while the corresponding change in the non-elderly group was −3.9 (95% CI −4.4 to −3.3); the between-group difference in this respect (0.3, 95% CI −1.0 to 1.5; p=0.688) was not statistically significant. Similar results were observed at weeks 2, 4, 6, 8, 10, 16, 18, 20, 24, 28, 30, 32 and 36 (p>0.05 for all). With respect to the mean change in AUL from baseline at weeks 2, 4, 6, and 12, both groups showed a progressive decrease over time; the between-group differences in this respect were not statistically significant at all time points (p>0.05 for all). The mean change in ICIQ-SF score from baseline at weeks 4, 6, 8, 12, 16, 18, 20, 24, 28, 30, 32 and 36 also showed a decreasing trend in both groups; however, there was no significant between-group difference in this respect (p>0.05 at all time points). The outcome measures are detailed in online supplementary appendix 2.2.

The incidence of adverse events related to EA treatment during the treatment period was 2.17% in the elderly group and 1.37% in the non-elderly group. No serious adverse events occurred in any of the groups. Details of adverse events during the two trials are displayed in table 3.

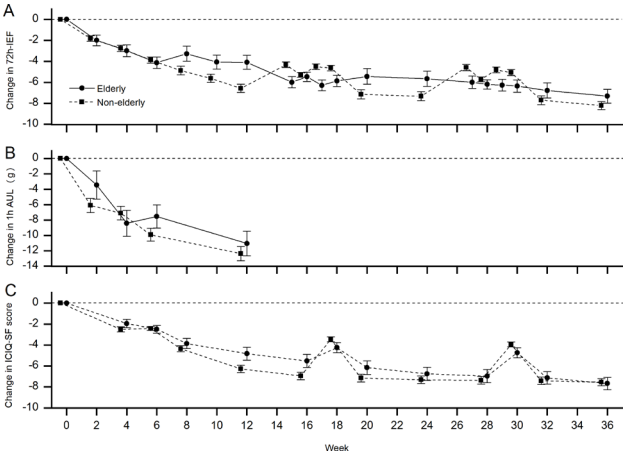

Figure 1 Changes in 72-hour IEF, 1-hour AUL and ICIQ-SF score from baseline at various time points.

AUL, amount of urine leakage; IEF, incontinence episode frequency; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

DISCUSSION

In this secondary analysis, we examined the data from two randomised controlled trials of SUI or stress-predominant MUI to compare the efficacy of EA in elderly and non-elderly women. The results showed no significant difference between the proportion of patients with ≥50% reduction in mean 72-hour IEF from baseline at week 6, with elderly group of 57.3% and the non-elderly group of 60.7%. Besides, the changes from baseline to the observed weeks in 72-hour IEF, AUL and the ICIQ-SF score in the elderly and non-elderly groups all had considerable reductions, with no between-group differences. The outcomes suggest that women with SUI or stress-predominant MUI show good response to EA and that the response is not correlated with age.

The effect comparisons of surgical treatment between older and younger cohorts have been reported in previous studies. Similar conclusions were shown in a review[19]: when compared with younger

Table 3 Adverse events*†

	Elderly (n=92)	Non-elderly (n=292)
EA-related adverse events		
Overall	2 (2.17)	4 (1.37)
Fatigue	0 (0.00)	2 (0.68)
Unbearable pain	1 (1.09)	0 (0.00)
Haematoma	1 (1.09)	2 (0.68)
EA-unrelated adverse events		
Overall	27 (29.35)	45 (15.41)
Upperrespiratory infection	2 (2.17)	12 (4.11)
Pneumonia	1 (1.09)	0 (0.00)
Cold	18 (19.57)	24 (8.22)
Pharyngitis	0 (0.00)	1 (0.34)
Chronic bronchitis	2 (2.17)	0 (0.00)
Cough	0 (0.00)	1 (0.34)
Dizziness	1 (1.09)	1 (0.34)
Headache	0 (0.00)	1 (0.34)
Herpes zoster	0 (0.00)	1 (0.34)
Diarrhoea	1 (1.09)	1 (0.34)
Facial oedema	0 (0.00)	1 (0.34)
Urinary tract infection	1 (1.09)	0 (0.00)
Uterine fibroids	0 (0.00)	1 (0.34)
Knee osteoarthritis	1 (1.09)	0 (0.00)
Others	0 (0.00)	1 (0.34)

*Adverse events were analysed for all patients who received treatment and were counted by type rather than frequency in the same patient. Adverse events of different types occurring in a single patient were defined as independent adverse events. A single adverse events type with multiple occurrences in a single patient was defined as one adverse event.

†Data are reported as no (%) unless otherwise indicated.

EA, electroacupuncture.

women, elderly women have almost similar outcomes after surgery, though they may have greater associated morbidity and a longer recovery period. Some subgroup analyses of randomised controlled trials showed that the elderly had poor response to surgical treatment. A study involving 970 women with SUI who underwent tension-free vaginal tape treatment showed that the subjective cure rate in elderly women was lower than that in non-elderly women.[13] Another research of 537 women comparing retropubic to transobturator tape found that increasing age was an independent risk factor for surgery failure.[20] Results of studies in non-operative treatment on elderly women with SUI are consistent with ours. Some studies of PFMT in elderly women found that in older patients with SUI, the outcome measures were comparable to those in the younger. The effect of PFMT in patients with SUI did not seem to decrease with age.[21–23] Two randomised controlled trials of tolterodine treatment in the elderly found a similar efficacy and side effect profile to the younger.[24 25] In our study, no significant between-group differences were observed with respect to most parameters. This implies that EA may improve SUI or stress-predominant MUI in women irrespective of the age.

We defined the proportion of patients with ≥50% decrease in the mean 72-hour IEF as the main outcome measured using the bladder diary; 50% reduction in IEF can be considered as the threshold for clinical significance in the treatment of SUI.[26] After 6-week EA treatment, a high percentage of women in both groups achieved ≥50% reduction in 72-hour IEF from baseline. In addition, in both the SUI and MUI trials, we had performed subgroup analysis of patients who achieved ≥50% decrease in mean 72-hour IEF disaggregated by age. At the corresponding time points (weeks 4, 6, 16 and 28), no significant between-group differences were observed in both the trials, which is consistent with the results of the present study. After EA treatment, the proportions of patients who had achieved ≥50% reduction in 72-hour IEF from baseline at week 28 were 73.03% in the elderly group and 70.21% in the non-elderly group; the outcomes are comparable to 69.98% at the endpoint after duloxetine treatment.[27]

The consistent changes were found in 72-hour IEF from baseline to the observed weeks in both the elderly and non-elderly groups. At week 12, the change was −4.1 (−5.4 to −2.8) and −6.6 (−7.3 to −5.8), respectively. A previous study investigated the effects of a pelvic floor muscle rehabilitation programme among elderly women with SUI (age >60 years); after 12-week intervention, the 3-day leakage episodes decreased from 4.6±4.2 to 1.1±1.6 (p=0.003), which were similar to our results.[28] Changes from the baseline of the AUL were measured by 1-hour pad test, which is used to quantify urine leakage due to SUI. Both groups showed good reduction in AUL at weeks 2, 4, 6 and 12; no significant between-group differences were observed in this respect at any of the time points. In a clinical trial of pelvic floor muscle treatment, the mean decrease in AUL at week 12 was 7.9 g (SD 12.1).[29] In comparison, EA treatment showed better efficacy as the mean decrease in AUL at week 12 in our secondary analysis was −11.1 g (−14.2 to −7.9) in the elderly group and −12.4 g (−14.2 to −10.5) in the non-elderly group. We also found good reductions in the ICIQ-SF score from baseline to the observed weeks in both groups; however, there were no significant between-group differences in this respect, either. In the two age groups, the reduction was greater than −2.52 (the minimal clinically important difference) (range, −2.4 to −7.7) at most time points with the exception of week 4 in the elderly group (−2.0). These results are comparable to that reported from a previous study of clinical symptoms improvement after pelvic floor muscle exercise.[30] In our study, we observed a low incidence of adverse events, and most events were mild and transient.

Continence is maintained by bladder wall stability, an intact pelvic floor and nerve supply to the bladder,

which also requires mobility, manual dexterity and the cognitive ability to react to bladder filling.[31] Weakness of pelvic floor muscles and bladder neck is the cause of SUI.[32] Age might be an important factor that affects the treatment outcomes in women with SUI. With age, physiological changes in the lower urinary tract can have a predisposition to SUI. The changes in ageing bladder include increased collagen content, changes to gap junctions, increased space between myocytes and the sensitivity of sensory afferents changes.[33] Bladder capacity and urethral closure pressure decrease, while the postvoid residual volume and overactivity of the detrusor muscle increase, which may lead to SUI.[34] The mechanism of action of EA may involve stimulation of S3 via BL33 and that of pudendal nerve via BL35, which promotes pelvic floor muscle contraction and augments muscle strength; this may partially explain our results.[35] Our results suggest that outcomes of EA therapy in women with SUI may not be affected by age. It may be inferred that compared with other therapeutic modalities, the efficacy of EA in women with SUI may not be affected by geriatric factors.

There were several limitations in our secondary analysis. First, the two trials actually had some differences that may have affected the outcomes of this study. These included the two diseases (SUI and stress-predominant MUI) are not exactly the same; the age range of participants (SUI trial: 40–75 years; MUI trial: 35–75 years) and the duration of treatment and follow-up. Second, potential bias cannot be ruled out because the secondary analysis was not predefined during the design of the primary studies. Lastly, our study population exclusively composed of Chinese women; therefore, our findings may not be applicable to other ethnic groups.

CONCLUSION

EA may have good effects in both elderly and non-elderly women with SUI or stress-predominant MUI. The age factor may not affect the treatment outcomes. Further large-scale studies are required to provide more definitive evidence and to explore the underlying mechanisms.

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REFERENCES

1 Abrams P, Cardozo L, Fall M, *et al*. The standardisation of terminology in lower urinary tract function: report from the standardisation Sub-committee of the International continence Society. *Urology* 2003;61:37–49.
2 Hunskaar S, Lose G, Sykes D, *et al*. The prevalence of urinary incontinence in women in four European countries. *BJU Int* 2004;93:324–30.
3 Myers DL. Female mixed urinary incontinence: a clinical review. *JAMA* 2014;311:2007–14.
4 Nambiar AK, Lucas MG. Pathophysiology of urinary incontinence. *Surgery* 2014;32:279–85.
5 Kobashi KC, Albo ME, Dmochowski RR, *et al*. Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline. *J Urol* 2017;198:875–83.
6 Lagro-Janssen T, Smits A, Van Weel C. Urinary incontinence in women and the effects on their lives. *Scand J Prim Health Care* 1992;10:211–6.
7 Qaseem A, Dallas P, Forciea MA, *et al*. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the American College of physicians. *Ann Intern Med* 2014;161:429–40.
8 Kielb SJ. Stress incontinence: alternatives to surgery. *Int J Fertil Womens Med* 2005;50:24–9.
9 Richter HE, Albo ME, Zyczynski HM, *et al*. Retropubic versus transobturator midurethral slings for stress incontinence. *N Engl J Med* 2010;362:2066–76.
10 Minassian VA, Drutz HP, Al-Badr A. Urinary incontinence as a worldwide problem. *Int J Gynaecol Obstet* 2003;82:327–38.
11 EAU Guidelines on Urinary Incontinence in Adults. European association of urology, 2019. Available: https://uroweb.org
12 Gordon D, Gold R, Pauzner D, *et al*. Tension-Free vaginal tape in the elderly: is it a safe procedure? *Urology* 2005;65:479–82.
13 Hellberg D, Holmgren C, Lanner L, *et al*. The very obese woman and the very old woman: tension-free vaginal tape for the treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;18:423–9.
14 Liu Z, Liu Y, Xu H, *et al*. Effect of electroacupuncture on urinary leakage among women with stress urinary incontinence: a randomized clinical trial. *JAMA* 2017;317:2493–501.
15 Liu B, Liu Y, Qin Z, *et al*. Electroacupuncture versus pelvic floor muscle training plus solifenacin for women with mixed urinary incontinence: a randomized Noninferiority trial. *Mayo Clin Proc* 2019;94:54–65.

16 Available at. Definition of an elderly or elderly person. Available: http:// www. who.int/healthinfo/survey/ageingdefnelderly/en/
17 Brown JS, McNaughton KS, Wyman JF, *et al*. Measurement characteristics of a voiding diary for use by men and women with overactive bladder. *Urology* 2003;61:802–9.
18 Huang L, Zhang S-wen, Wu S-liang, *et al*. The Chinese version of ICIQ: a useful tool in clinical practice and research on urinary incontinence. *Neurourol Urodyn* 2008;27:522–4.
19 Robinson D, Castro-Diaz D, Giarenis I, *et al*. What is the best surgical intervention for stress urinary incontinence in the very young and very old? an international consultation on incontinence research Society update. *Int Urogynecol J* 2015;26:1599–604.
20 Barber MD, Kleeman S, Karram MM, *et al*. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. *Am J Obstet Gynecol* 2008;199:666.e1–666.
21 Kim H, Suzuki T, Yoshida Y, *et al*. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomized, controlled, crossover trial. *J Am Geriatr Soc* 2007;55:1932–9.
22 Sherburn M, Bird M, Carey M, *et al*. Incontinence improves in older women after intensive pelvic floor muscle training: an assessor-blinded randomized controlled trial. *Neurourol Urodyn* 2011;30:317–24.
23 McFall SL, Yerkes AM, Cowan LD, *et al*. Outcomes of a small group educational intervention for urinary incontinence: health-related quality of life. *J Aging Health* 2000;12:301–17.
24 Zinner NR, Mattiasson A, Stanton SL, *et al*. Efficacy, safety, and tolerability of extended-release once-daily tolterodine treatment for overactive bladder in older versus younger patients. *J Am Geriatr Soc* 2002;50:799–807.
25 Drutz HP, Appell RA, Gleason D, *et al*. Clinical efficacy and safety of tolterodine compared to oxybutynin and placebo in patients with overactive bladder. *Int Urogynecol J Pelvic Floor Dysfunct* 1999;10:283–9.
26 Yalcin I, Peng G, Viktrup L, *et al*. Reductions in stress urinary incontinence episodes: what is clinically important for women? *Neurourol Urodyn* 2010;29:344–7.
27 Lin AT-L, Sun M-J, Tai H-L, *et al*. Duloxetine versus placebo for the treatment of women with stress predominant urinary incontinence in Taiwan: a double-blind, randomized, placebo-controlled trial. *BMC Urol* 2008;8:2.
28 Madill SJ, Pontbriand-Drolet S, Tang A, *et al*. Changes in urethral sphincter size following rehabilitation in older women with stress urinary incontinence. *Int Urogynecol J* 2015;26:277–83.
29 Liebergall-Wischnitzer M, Hochner-Celnikier D, Lavy Y, *et al*. Randomized trial of circular muscle versus pelvic floor training for stress urinary incontinence in women. *J Womens Health* 2009;18:377–85.
30 Sjöström M, Umefjord G, Stenlund H, *et al*. Internet-Based treatment of stress urinary incontinence: 1- and 2-year results of a randomized controlled trial with a focus on pelvic floor muscle training. *BJU Int* 2015;116:955–64.
31 Thirugnanasothy S. Managing urinary incontinence in older people. *BMJ* 2010;341:c3835–343.
32 Parazzini F, Chiaffarino F, Lavezzari M, *et al*. Risk factors for stress, urge or mixed urinary incontinence in Italy. *BJOG* 2003;110:927–33.
33 Siroky MB. The aging bladder. *Rev Urol* 2004;6 Suppl 1:S3–7.
34 Bracewell C, Gray R, Rai GS. *Essential facts in geriatric medicine*. Radcliffe Publishing, 2005.
35 Wang S, Zhang S. Simultaneous perineal ultrasound and vaginal pressure measurement prove the action of electrical pudendal nerve stimulation in treating female stress incontinence. *BJU Int* 2012;110:1338–43.

Ethical approvals of all participating hospitals

This trial is to be conducted in 12 hospitals. The ethical review was firstly submitted to IRB of the principle organization, Guang'an men Hospital, and then to IRB of other participating hospitals. This trial has gained approval from all of the IRBs.

Ethical approvals are attached in the following sequence.

1. Guang'an men Hospital, China Academy of Chinese Medical Sciences
2. Xiyuan Hospital of China Academy of Chinese Medical Sciences
3. Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine
4. Yueyang Hospital of Integrated Traditional Chinese and Western Medicine affiliated to Shanghai University of Traditional Chinese Medicine
5. West China Hospital of Sichuan University
6. First Teaching Hospital of Tianjin University of TCM
7. First Hospital of Hunan University of Chinese Medicine
8. Hengyang Hospital affiliated to Hunan University of Chinese Medicine
9. Hubei Provincial Hospital of TCM
10. Jiangsu Province Hospital of TCM
11. Shanxi Province Hospital of TCM
12. Shanxi Hospital of Integrated Traditional and Western Medicine

Attachment 1: Ethical approval of Guang'an men Hospital, China Academy of Chinese Medical Sciences

中国中医科学院广安门医院伦理委员会文件（EC_AF_022）

伦理审查批件

项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
项目编号	2012EC007	项目来源	“十二五”国家科技支撑计划
牵头单位	中国中医科学院广安门医院		
申办者（如有）	/		
主要研究者	刘志顺		
审查类别	初始审查	审查方式	会议审查
审查日期	2012.12.14	审查地点	广安门医院行政楼四楼会议室
审查委员	殷海波，朴炳奎，林兰，谢利民，曹炜，冯玲，赵军，胡镜清，吴萍，顾丽贞，沈瑞英		
批准文件	研究方案（VERSION 1.0_20121105），知情同意书（V1.0）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。		
有效期	2012 年 12 月 20 日～2013 年 12 月 19 日		
联系人与联系电话	乔洁 010-88001552		
主任委员签字			
中国中医科学院广安门医院伦理委员会（盖章）			
日期：2012 年 12 月 21 日			

版本号：1.00 / 版本日期：20121106

第 1 页/共 1 页

Institutional Review Board Documentation of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (EC_AF_022)

Ethics Approval of Guang'anmen Hospital of China Academy of Chinese Medical Sciences

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Approval No.	2012EC007	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Leading Organization	Guang'anmen Hospital of China Academy of Chinese Medical Sciences		
Applicant (if any)	/		
Site PI	Zhishun Liu		
Review Attribute	Initial Review	**Review Methods**	Review Conference
Review Date	Sep 14, 2012	**Review Place**	Conference Room, the 4th Floor of the Administrative Building of Guang'anmen Hospital
Review Committee	Haibo Yin, Bingkui Piao, Lan Lin, Limin Xie, Wei Cao, Ling Feng, Jun Zhao, Jingqing Hu, Ping Wu, Lizhen Gu, Ruiying Shen		
Approved Files	Study Protocol (VERSION 1.0_20121105), Informed Consent (V1.0)		
Review Comments	According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki", and "International ethical guidelines for biomedical research involving human subjects" issued by Council for International Organizations of Medical Sciences, this clinical research was reviewed by the institutional review board (IRB) of Guang'anmen Hospital of China Academy of Chinese Medical Sciences. And the study protocol, informed consent, and the		

Institutional Review Board Documentation of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (EC_AF_022)

	recruitment files of this research were approved. Please conduct this clinical study following the GCP principles and the study protocol approved by the IRB. The health and rights of the subjects should be protected throughout the whole study. An application should be submitted if a change of the principle investigator (PI), or any modification of the study protocol, informed consent, or the recruitment files are made. A report of the severe adverse events (SAE) should be submitted in time if any SAE or any other un-anticipated AE, which will affect the risk-reward ratio of this study, occurs. Researchers should submit report of the study progress one month before the deadline according to ethical review frequency. A summary report of the study progress of each site should be submitted by the site PI to the IRB of the leading site. In any condition which will greatly affect the progress of the study or increase the potential risk of the subjects, a written report should be submitted by the site PI to the IRB. A protocol deviation report should be submitted by the site PI/monitor/researcher if any of the following occurs: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria, were wrongly included in the study; subjects do not withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected. A final report should be submitted when the study is finished completely or terminated prematurely.
Validity Period	From Dec 20, 2012 to Dec 19, 2013
Contact	Jie Qiao, +86 010 88001552
Director Signature	Haibo Yin
IRB of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (Seal)	
Data: Dec 21, 2012	

Version No. 1.00 / Version Date Nov 06, 2012

Attachment 2: Ethical approval of Xiyuan Hospital of China Academy of Chinese Medical Sciences

中国中医科学院西苑医院医学伦理委员会审查批件

批件号：中国中医科学院西苑医院医学伦理委员会 **2013XL001-2**

审查日期	2013 年 1 月 25 日
审查地点	北京海淀区西苑操场 1 号中国中医科学院西苑医院医学伦理委员会
课题编号	2012BAI24B01
项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性 ——多中心随机对照试验
审查文件	伦理审查申请书、研究者手册、研究者履历、CRF、患者日记等； 研究方案：版本号：VERSION 1.0_20121106，版本日期：2012 年11 月6 日 修正的知情同意书:版本号:VERSION 1.0 20120220，版本日期：2013 年2 月20 日
课题组织单位	国家科技部“十二五”国家科技部
临床研究单位	中国中医科学院广安门医院、北京中医药大学东直门医院、 四川大学华西医院、中国中医科学院西苑医院、湖南中医药大学附属衡阳医院、湖南省中医院、上海中医药大学附属岳阳中西医结合医院、天津中医药大学第一附属医院、陕西省中医医院、江苏省中医院、山西中医学院中西医结合医院、湖北省中医院
主要研究者	陆永辉（副主任医师） -本中心
会议审查委员	曹云、衷敬柏、尚晓泓、尹秀云、张广生、杨志旭、于振宣、韩梅、李涛、房定亚、闫小平
审查意见	根据中华人民共和国国家药品食品监督管理局 2003 年颁布实施的《药物临床试验质量管理规范》、2010 年 11 月颁布的《药物临床试验伦理审查工作指导原则》以及《赫尔辛基宣言》的伦理原则，经本伦理委员会会议审查，审查结果为“作必要的修正后同意”，具体意见如下： （1）主要研究者符合国家相关规定； （2）研究方案的设计基本符合科学性、伦理性原则。临床筛选患者做残余尿检查时不应让患者大量饮水。 （3）修正后的知情同意书语言通俗易懂，信息充分。 （4）给予伦理审查批件。如临床试验方案有任何修改，主要研究者更换等，需重新审查，获得批准后执行。 暂停/提前终止/完成临床研究，请及时通知伦理委员会。 **本批件有效期一年，请于 2014 年 2 月 21 日前 1 个月提交跟踪审查申请报告。** 发现影响受试者参加研究意愿的违反方案情况应及时报告
联系电话	伦理委员会秘书 訾明杰（010）62835646
主任委员	曹云
盖　章	中国中医科学院西苑医院医学伦理委员会
日　期	2013 年 2 月 22 日

Ethics Approval of Xiyuan Hospital of China Academy of Chinese Medical Sciences

Approval Number: Institutional Review Board of Xiyuan Hospital of China Academy of Chinese Medical Sciences 2013XL001-2

Review Date	Jan 25, 2013
Review Place	Institutional Review Board of Xuyuan Hospital of China Academy of Chinese Medical Sciences, 1 Xiyuan Playground, Haidian, Beijing
Project No.	2012BAI24B01
Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial
Approval Files	Application Form of Ethical Review, Researchers' Handbook, Researchers' CV, CRF, Patients' Diary, etc. Study Protocol: Version No. VERSION 1.0_20121106; Version Date Nov 6, 2012 Revised Informed Consent: Version No. VERSION 1.0 20120220; Version Date Feb 20, 2013
Project Sponsor	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Clinical Sites	Guang'anmen Hospital of China Academy of Chinese Medical Sciences, Dongzhimen Hospital of Beijing University of Chinese Medicine, West China Hospital of Sichuan University, Xiyuan Hospital of China Academy of Chinese Medical Sciences, Hengyang Hospital of Hunan University of Chinese Medicine, the Second Affiliated Hospital of Hunan University of Chinese Medicine, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine of Shanghai University of Traditional Chinese Medicine, the First Affiliated Hospital of Tianjin University of Chinese Medicine, Shaanxi Province Hospital of TCM, Jiangsu Province Hospital of TCM, Shanxi Hospital of Integrated Chinese and Western Medicine, Hubei Province Hospital of TCM
Site PI	Yonghui Lu (our center)
Review Committee	Yun Cao, Jingbo Zhong, Xiaohong Shang, Xiuyun Yin, Guangsheng Zhang, Zhixu Yang, Zhenxuan Yu, Mei Han, Tao Li, Dingya Fang, Xiaoping Yan
Review Comments	According to the "Good Clinical Practice" issued by the State Food and Drug Administration of the People's Republic of China in 2003, the "Guidelines for Ethical Review Work of Drug Clinical Trials" issued in Nov, 2010, and the "Declaration of Helsinki", though our Review Conference, the results of this review was "agreed after revision", detailed comments are as following: (1) the site PI selected meets the correlated national regulation; (2) the design of this study protocol was scientific and ethical; For doing the residual urine volume, patients should not be required to drink water generously; (3) the revised informed consent was straightaway and informative;

	(4) the documentations were approved by the IRB, if any revision of the study protocol, or a change of the main researcher was made, a new ethics review will be needed. Please inform the IRB in time if the study was paused/stopped prematurely/completed. This approval stands good for 1 year, please submit an application of continuing review 1 month before Feb 21, 2014. Please report in time if the condition that violate the study protocol occurs.
Contact Phone	Secretary of the IRB: Mingjie Zi +86 010 62835646
Committee Director	Yun Cao
Seal	Institutional Review Board of Xiyuan Hospital of China Academy of Chinese Medical Sciences
Date	Feb 22, 2013

Attachment 3: Ethical approval of Xiyuan Hospital of China Academy of Chinese Medical Sciences

北京中医药大学东直门医院医学伦理委员会
IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

伦理审查批件

Approval Notice Template

受理序号：ECSL-BDY-2013-04　　批件号：ECPJ-BDY-2013-04

项目名称：电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验

申办单位：东直门医院　　主要研究者：赵吉平

项目类别：国家科技支撑项目　　批文号/课题编号：2012BAI24B01

方案版本号：1.0_20121105　　方案批准日期：2012.11.5

知情同意书版本号：V1.0　　知情同意书批准日期：2012.11.5

伦理审查方式：☑会议审查　☐快速审查

应到会 15 人，出席本次会议人员 9 人，回避 0 人，缺席 6 人

根据中华人民共和国国家食品药品监督管理局（SFDA）《药物临床试验伦理审查工作指导原则》（2010 年）、《药物临床试验质量管理规范》（2003）、《中药品种保护指导原则》（2009），世界医学会《赫尔辛基宣言》（2008），卫生部《涉及人的生物医学研究伦理审查办法》（2007），国家中医药管理局《中医药临床研究伦理审查管理规范》（2010）以及国际医学科学组织委员会《人体生物医学研究国际道德指南》（2002）的伦理原则，经本伦理委员会审查决定：	☑同意临床研究方案 ☐不同意临床研究方案 ☐终止临床研究方案 ☐暂停临床研究方案

审查意见：

同意临床研究

注：本批件自签发日期有效期一年，研究负责人必须严格使用经审查同意的知情同意书文本和研究方案。如伦理审查批件失效时不能完成所有的临床研究（包括统计分析），请在本批件失效前一个月，递交持续审查申请。如研究结束并在审查有效期内，请递交研究结题报告。研究中发生涉及受试者或其他人风险的任何预期或非预期的不良事件，应立刻报告本伦理委员会；任何研究方案、知情同意书的修改包括研究人员得变更，必须递交研究方案修改申请表，经伦理委员会审查获得批准后执行。

主任委员☑副主任委员☐签字：　　时 间：2015年 7月 5 日

北京中医药大学东直门医院医学伦理委员会　　地 点：第一会议室

本项目持续审查频率☐3个月 ☐6个月 ☑12个月　联系人：商建伟 （010）84013229

J. Support. Palliat Care 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

北京中医药大学东直门医院医学伦理委员会

IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

会议签到表

Meeting attendance sheet

项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
会议时间	2月 1日	会议地点	第一会议室

成员	性别	伦理委员会职务	专业	签名
李澎涛	男	主任	脑病	
高　颖	女	副主任	脑病	
叶永安	男	副主任	消化	
柳红芳	女	副主任	肾病内分泌	
张永涛	男	委员	呼吸	
王新月	女	委员	消化	
杨博华	男	委员	周围血管	
鲁卫星	男	委员	心血管	
王蓬文	女	委员	药理学	
曹俊岭	男	委员	药剂学	
刘　凯	男	委员	法律代表	
贺海东	男	委员	医疗器械	
张胜利	男	委员	群众代表	
陈信义	男	委员	血液肿瘤	
彭淑莲	女	委员	乳腺外科	

Institutional Review Board of Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine

Approval Notice Template

Accepted No. ECSL-BDY-2013-04 **Approval No.** ECPJ-BDY-2013-04

Project Title: The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial	
Application Center: Dongzhimen Hospital	**Site PI:** Jiping Zhao
Project Attribute: the National Key Technology Support Program	**Project No.** 2012BAI24B01
Protocol Version No. 1.0_20121105	**Protocol Approval Date:** Nov 5, 2012
Informed Consent No. V1.0	**Informed Consent Approval Date:** Nov 5, 2012
Review Method: □√ Review Conference □ Quick Review	
Member: Anticipated 15 persons, participated 9 persons, avoided 0 persons, absented 6 persons.	
According to the "Guidelines for Ethical Review Work of Drug Clinical Trials" (2010), the "Good Clinical Practice" (2003), the "Guiding Principle of Herb Variety Protection" (2009) issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Declaration of Helsinki" (2008), the "ethical review methods for biomedical study involving human subjects" (2007) issued by the Ministry of Health, the "Management specifications for ethical review of TCM clinical studies" (2010) issued by State Administration of Traditional Chinese Medicine, and the "International ethical guidelines for biomedical research involving human subjects" (2002) issued by Council for International Organizations of Medical Sciences, our IRB agreed that:	□√ approved □ not approved □ terminated □ paused
Review Comments: **APPROVED** **Note:** The validity of this approval is 1 year. Site PI must abide by the approved documents. If the trial could not accomplish before the validity (including the statistical analysis), please submit for continuing review 1 month before the deadline. If the trial accomplished in the validity, please submit the final report. If there is any adverse event related to the trial occurred, please reported to the committee. If there is any change about the protocol, informed consent, or investigators, modification application must be submitted to the committee and get approved.	
Director□√ Assistant Director□ **Signature:**	**Date:** Feb 5, 2013
Institutional Review Board of Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine	**Place:** the 1st meeting room
Continuing Review Frequency: □ 3 mon □ 6 mon □√12 mon	**Contact:** Jianwei Shang +86 010 84013229

Institutional Review Board of Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine

Meeting Attendance Sheet

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Meeting Date	Feb 1, 2013	**Meeting Place**	the 1st meeting room of Dongzhimen Hospital

Member	**Gender**	**Position**	**Major**	**Signature**
Pengtao Li	Male	Director	Cerebropathy	
Ying Gao	Female	Assistant Director	Cerebropathy	
Yong'an Ye	Male	Assistant Director	Gastroenterology	
Hongfang Liu	Female	Assistant Director	Nephropathy Endocrine	
Yongtao Zhang	Male	Committee Member	Respirology	
Xinyue Wang	Female	Committee Member	Gastroenterology	
Bohua Yang	Male	Committee Member	Surrounding blood-vessel	
Weixing Lu	Male	Committee Member	Angiocardiopathy	
Pengwen Wang	Female	Committee Member	Pharmacology	
Junling Cao	Male	Committee Member	Pharmacy	
Kai Liu	Male	Committee Member	Legal Representative	
Haidong He	Male	Committee Member	Medical Equipment	
Shengli Zhang	Male	Committee Member	People's Representative	
Xinyi Chen	Male	Committee Member	Hemooncology	
Shulian Peng	Female	Committee Member	Breast Surgery	

Attachment 4: Ethical approval of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine affiliated to Shanghai University of Traditional Chinese Medicine

上海中医药大学附属岳阳中西医结合医院伦理委员会

IRB of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM

伦理审查批件

Approval Notice Template

伦理审议批件号：上海中医药大学附属岳阳中西医结合医院伦理委员会 2013 伦理审查 033 号 (2013-033)

研究名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
研究类型	临床试验	研究周期	两年
研究单位和研究者	上海中医药大学附属岳阳中西医结合医院　陈跃来		
伦理委员会审议成员	金利国、王雪文、徐玲玲、史晓、常时新、陈云飞、樊民胜、周正、任力		
伦理委员会地址	上海市虹口区甘河路 110 号		
审议时间	2013 年 4 月 27 日		
审议结论	根据中华人民共和国国家药品监督管理局 2003 年颁布实施的《药物临床试验质量管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的道德原则。本伦理委员会的全体成员审阅并讨论了下列有关材料： 1、临床课题伦理审查申请表 2、研究方案（1.0 2012.11.06） 3、知情同意书（2.0 2013.05.10） 4、主要研究者简历 5、招募广告 6、CRF 表（1.0 2012.11.09） 7、研究人员名单 8、其他资料：病例筛选表；尿垫使用情况记录表；排尿日记； 本伦理委员会经表决同意你们自即日起开展“电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验”； 并要求：上述资料未经本委员会批准，不得作任何修改；试验过程中如发生严重不良事件，应立即（24 小时内）报告本委员会；如临床试验方案、知情同意书及研究者有任何更改，应及时通知伦理委员会，得到重新批准。		
主任委员签字			
备注	该批件有效期一年，自批件生效日起 12 月内未完成研究的，请向伦理委员会提交跟踪审查申请。 联系人：肖夏懿 电话：65161782*2419		

上海中医药大学附属岳阳中西医结合医院

医学伦理委员会（盖章）

2013 年 5 月 20 日

上海中医药大学附属岳阳中西医结合医院伦理委员会

IRB of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM

会议签到表

Sign-in Sheet of Full Board Meeting

会议日期：2013 年 4 月 27 日

审查项目：电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验

伦理委员会到会委员签名：

姓名	性别	专业情况	签名
金利国	男	医学、管理	
陈云飞	男	医学	
常时新	男	医学	
徐玲玲	女	药学	
史　晓	女	中医学	
王雪文	女	护理学	
樊民胜	男	社会科学、伦理学	
周　正	男	法律	
任　力	男	法律	

Institutional Review Board of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM

Approval Notice Template

Approval No. IRB of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM 2013 Ethics Approval No. 003 (2013-033)

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: A Multicenter, Randomized Controlled Trial		
Research Attribute	Clinical Trial	**Research Period**	2 years
Site and Site PI	Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM Yuelai Chen		
Review Committee	Liguo Jin, Xuewen Wang, Lingling Xu, Xiao Shi, Shixin Chang, Yunfei Chen, Minsheng Fan, Zheng Zhou, Li Ren		
IRB Address	110 Ganhe Road, Hongkou, Shanghai		
Review Date	Apr 27, 2013		
Review Comments	According to the "Good Clinical Practice" issued by State Food and Drug Administration (SFDA) of the People's Republic of China in 2003, "Declaration of Helsinki", and the "International ethical guidelines for biomedical research involving human subjects" issued by Council for International Organizations of Medical Sciences, all the members of our IRB reviewed and discussed the files as following: 1. Ethics Approval Application Form of Clinical Trial 2. Study Protocol (1.0 2012.11.06) 3. Informed Consent (2.0 2013.05.10) 4. Main Researchers' CV 5. Recruiting Advertisement 6. CRF (1.0 2.12.11.09) 7. All Researchers' List 8. Other Files: Case Screening Form, Recording Sheet of the Urinal Pad Using, Urination Diary The IRB approved your study "The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: A Multicenter, Randomized Controlled Trial" through voting; The files listed above are not allowed to modify unless a permission was obtained from our IRB; Any severe adverse event occurred during the study should be reported to the IRB within 24 hours; If there is any change about the protocol, informed consent, or investigators, modification application must be submitted to the committee and get approved.		
Director Signature			
Note	The validity of this approval is one year, if the trial could not accomplish before the validity, please submit for continuing review before the deadline. **Contact:** Xiayi Xiao **Phone:** +86 021 65161782-2419		

Institutional Review Board of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM

Sign-in Sheet of Full Board Meeting

Meeting Date: Apr 27, 2013

Project Title: The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: A Multicenter, Randomized Controlled Trial

Committee Signature:

Name	**Gender**	**Major**	**Signature**
Liguo Jin	Male	Medicine, Management	
Yunfei Chen	Male	Medicine	
Shixin Chang	Male	Madicine	
Lingling Xu	Female	Pharmacy	
Xiao Shi	Female	Traditional Chinese Medicine	
Xuewen Wang	Female	Nursing	
Minsheng Fan	Male	Social Sciences, Ethics	
Zheng Zhou	Male	Law	
Li Ren	Male	Law	

Attachment 5: Ethical approval of West China Hospital of Sichuan University

四川大学华西医院临床试验与生物医学伦理专委会审查批件

2013年 审（7）号

科室（专业）： 中西医结合科	项目负责人姓名及职称： 李宁 副主任医师	
项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性—多中心随机对照试验	
研究方案	版本号：无	版本日期：2013.1.7
知情同意书	版本号：修订版	版本日期：2013.1.29

审查意见：

1. 研究者资质符合伦理要求。
2. 研究方案及知情同意书基本符合伦理要求。

审查结果： ■同意 □作必要修正后同意 □修正后再审 □不同意 □终止或暂停

请遵循我国相关法律、法规和规章（SFDA《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定》（2004）、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》、卫生部《涉及人的生物医学研究伦理审查办法（试行）（2007）》），遵循伦理委员会批准的方案和知情同意书开展临床试验（研究），保护受试者的健康与权利。

在试验（研究）过程中，若变更主要研究者，对临床研究方案、知情同意书等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告；紧急报告之后，尽快提交详细的严重不良事件随访报告。

请递交年度和定期跟踪审查报告；当出现任何可能显著影响试验（研究）进行或增加受试者危险的情况时，请申请人及时向伦理专委会提交书面报告。

试验（研究）纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验（研究）规定而未让受试者退出试验（研究），给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背伦理原则与规范的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床试验（研究），请及时提交暂停/终止试验（研究）报告。完成临床试验（研究），请申请人提交结题报告。

单位（章）：

主任委员（签名）：

2013 年 2 月 22 日

Sun B, *et al. BMJ Support Palliat Care* 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

Institutional Review Board of West China Hospital of Sichuan University

Ethics Review Approval

Approval No. 2013-7

Department:	Integrated Traditional Chinese and Western Medicine	**Site PI:**	Ning Li Associate Chief Physician
Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Study Protocol	**Version No.** /	**Version Date:** Jan 07, 2013	
Informed Consent	**Version No.** the Edited Version	**Version Date:** Jan 29, 2013	

Review Comments:

1. The Site PI selected met the requirements of ethics.
2. The study protocol and informed consent met the requirements of ethics.

Review Result: ■ approved ☐ approved after revision ☐ reviewed again after revision ☐ not approved ☐terminated or suspended

Researchers must obey the related laws and regulations such as SFDA "Good Clinical Practice (2003)", "Provisions for Clinical Trials of Medical Device (2004)", WMA "Declaration of Helsinki", CIOMS "International ethical guidelines for biomedical research involving human subjects (2007)". The study should perform according to the protocol and informed consent approved by this IRB. The health and right of the subjects should be protected.

If a change of the Site PI, or any modification of the protocol/informed consent was made, a new ethics approval application of the modified files must be submitted.

Researchers should report the severe adverse event (SAE) in time if any SAE occurred during the study. After the report, a detailed follow-up report of the SAE should also be submitted in time.

Please submit the annual or regular follow-up review report in time. In any condition which will greatly affect the progress of the study or increase the risk of the subjects, a written report should be submitted to the IRB.

The applicant/monitor/researcher should submit a protocol deviation report if any of the following

condition occurs: 1) subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly included in the study; 2) subjects do not withdraw from the study when he/she meet the rules of withdrawal; 3) incorrect treatment or dose was given; 4) prohibited combined medicine was used; 5) subjects' rights and health are badly affected; 6) the science of study was badly affected.

A concluding report should be submitted when the study is completely done or stopped prematurely.

IRB of West China Hospital of Sichuan University

Director Signature:

Date: Feb 22, 2013

Attachment 6: Ethical approval of First Teaching Hospital of Tianjin University of TCM

项目名称：电针治疗女性尿失禁临床试验 受理号：SLK2013001

天津中医药大学第一附属医院医学伦理委员会
IEC of The First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine

审 查 批 件

Approval Notice

伦理批件号：TYLL2013[E]字 001

根据卫生部《涉及人的生物医学研究伦理审查办法》（2007）、国家中医药管理局《中医药临床研究伦理审查管理规范》（2010）、国家食品药品监督管理局《药物临床试验伦理审查工作指导原则》（2010）、《药物临床试验质量管理规范》（2003），以及世界医学会《赫尔辛基宣言》（2008）、国际医学科学组织理事会《人体生物医学研究国际伦理指南》（2002）的伦理原则，经天津中医药大学第一附属医院医学伦理委员会 2013 年 3 月 8 日快速审查，同意由申办者天津中医药大学第一附属医院和主要研究者傅立新共同申请的电针治疗女性单纯性压力性尿失禁有效性和安全性-多中心随机对照试验项目开展临床研究工作。

请申办者、研究人员严格遵循 GCP 规定和本伦理委员会批准的方案（版本号：VERSION1.0_20121106 版本日期：20121106）、知情同意书（版本号：VERSION1.0_20121106 版本日期：20121106）开展临床研究。在研究开始前，须完成临床试验注册。该项目进行中如发生下列情况，须及时书面报告本伦理委员会：①对临床方案、知情同意书等的任何修改；②更换主要研究者；③发生严重不良事件；④出现任何可能影响试验进行或增加受试者危险的情况；⑤出现违反方案情况；⑥暂停或提前终止临床研究。

本伦理委员会将对该项目跟踪审查。

请于 2014 年 3 月 8 日前 1 个月提交研究进展报告。

该项目完成后，请向本伦理委员会提交结题报告。

本批件有效期为 2013 年 3 月 8 日至 2016 年 3 月 8 日。

天津中医药大学第一附属医院医学伦理委员会

主任委员签字：张金瑾

日 期：2013.3.8

联系人：贾景蕴 联系电话：022-27432276

Project Title: Acupuncture for Female Urinary Incontinence **Accepted No.** SLK2013001

IEC of The First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine

Approval Notice

Approval No. TYLL2013[E] 001

According to the "ethical review methods for biomedical study involving human subjects" (2007) issued by the Ministry of Health, "Good Clinical Practice" (2003) and "Guidelines for Ethical Review Work of Drug Clinical Trials" (2010) issued by the State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, WMA "Declaration of Helsinki" (2008), "International ethical guidelines for biomedical research involving human subjects" (2002) issued by Council for International Organizations of Medical Sciences, through the fast review from the IEC of the First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine, the research of "The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial" applied by the First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine and Lixin Fu was approved to perform.

The applicant and researchers should strictly abide by the GCP, the approved protocol (VERSION 1.0_20121106, Version Date: Nov 6, 2012), and the approved informed consent (VERSION 1.0_20121106, Version Date: Nov 6, 2012). The applicant/researcher should register this clinical trial before the performance of the study. Written report should submit to our IEC if any of the following occurs: 1) any modification of the study protocol, or the informed consent; 2) change of the site PI; 3) sever adverse event occurs; 4) subjects' rights and health are badly affected; 5) protocol deviation; 6) research paused or terminated prematurely.

Our IEC will continue reviewing the research.

The report of the study progress should be submitted 1 month before Mar 8, 2014.

Final report should be submitted after the research completion.

The validity of this approval ranges from Mar 8, 2013 to Mar 8, 2016.

IEC of The First Affiliated Hospital of Tianjin University of Traditional Chinese Medicine

Director Signature: Jinzhong Zhang

Date: Mar 08, 2013

Contact: Jingyun Jia **Phone:** +86 022 27432276

Attachment 7: Ethical approval of First Hospital of Hunan University of Chinese Medicine

编号：AF/SC-08/01.0

伦理审查批件

批件号	湖南中医药大学第一附属医院伦理委员会 HN-LL-KY-2013-001-01		
项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性-多中心随机对照试验		
项目来源	“十二五”国家科技支撑计划 2012BAI24B01		
研究单位	中国中医科学院广安门医院、湖南中医药大学第一附属医院等		
主要研究者	章薇		
审查类别	初始审查	审查方式	会议审查
审查日期	2013.1.23	审查地点	医院会议室
审查委员	郭志华，贺菊乔，赵艳玲，陈其华，黄孟君，张志国，张月娟，谭　劲，谢海波，钟　晓，管小平		
批准文件	临床研究方案（版本号:VERSION1.0-20121106） 知情同意书（版本号: VERSION1.0-201201109）		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

Sun B, *et al*. *BMJ Support Palliat Care* 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

完成临床研究，请申请人提交结题报告。	
年度/定期跟踪审查频率	12 个月
有效期	自批件下发之日起一年内有效
联系人与联系电话	赵鸿　王华 0731-85369233
主任委员签字	
伦理委员会	湖南中医药大学第一附属医院伦理委员会　（盖章）
日期	2013 年 1 月 24 日

湖南中医药大学第一附属医院伦理委员会

审查会议签到表

日期：2013年1月23日

伦理委员会到会委员签名：

姓名	性别	专业情况	签名
郭志华	男	湖南中医药大学第一附属医院 心血管内科　主任医师　教授	
贺菊乔	男	湖南中医药大学第一附属医院 中医外科　主任医师　教授	
赵艳玲	女	湖南中医药大学第一附属医院 主任医师　教授	
陈其华	男	湖南中医药大学第一附属医院 中医外科　主任医师　教授	
黄孟君	男	湖南中医药大学第一附属医院 中医消化　教授	
张月娟	女	湖南中医药大学第一附属医院 护理　主任护师　教授	
张志国	男	湖南中医药大学第一附属医院 药学　主任药师　教授	
谭劲	男	湖南中医药大学第一附属医院 中西医结合口腔　主任医师　教授	
谢海波	男	湖南中医药大学第一附属医院 中医内科　副主任医师　副教授	
管小平	男	律师，融源律师事务所	
钟晓	女	保险 太平人寿湖南分公司，业务经理	
赵鸿（秘书）	女	湖南中医药大学第一附属医院 护理　副主任护师　副教授	

Institutional Review Board of the First Affiliated Hospital of Hunan University of Chinese Medicine

No. AF/SC-08/01.0

Ethics Review Approval

Accepted No.	Institutional Review Board of the First Affiliated Hospital of Hunan University of Chinese Medicine HN-LL-KY-2013-001-01		
Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Project Sponsor	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China 2012BAI24B01		
Research Site	Guang'anmen Hospital of China Academy of Chinese Medical Sciences, the First Affiliated Hospital of Hunan University of Chinese Medicine		
Site PI	Wei Zhang		
Review Attribute	Initial Review	**Review Methods**	Review Conference
Review Date	Jan 23, 2013	**Review Place**	Meeting Room of the Hospital
Review Committee	Zhihua Guo, Juqiao He, Yanling Zhao, Qihua Chen, Mengjun Huang, Zhiguo Zhang, Yuejuan Zhang, Jin Tan, Haibo Xie, Xiao Zhong, Xiaoping Guan		
Approved Files	Study Protocol (Version No. VERSION 1.0-20121106) Informed Consent (Version No. VERSION 1.0-201201109)		

Review Comments

According to the "ethical review methods for biomedical study involving human subjects" (2007) issued by the Ministry of Health, "Good Clinical Practice" (2003) and "Provisions for Clinical Trials of Medical Device" (2004) issued by SFDA, WMA "Declaration of Helsinki", and the COIMS "International ethical guidelines for biomedical research involving human subjects", through the review of our IRB, the study protocol, informed consent, and related recruitment files were approved.

Please conform to the principle of GCP, and conform to the protocol approved by our IRB, and protect the health and rights of the subjects.

The applicant or PI should register this clinical trial online before the start of the study.

An application should be submitted if a change of the site PI, or any modification of the study protocol, informed consent, or the recruitment files are made.

The report of the severe adverse event (SEA) should be submitted in time if any SAE occurs.

Please do the follow-up review annually or termly according to the stipulation of our IRB. The report of the study progress should be submitted one month before the deadline. A summary report of the study progress should be submitted to the IRB of the leading site. In any condition which will greatly affect the study progress or increase the potential risk of the subjects, a written report should be submitted by the applicant/researcher to IRB.

A protocol violation report should be submitted by the applicant/monitor/researcher in the following conditions: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly included in the study; subjects do not

Institutional Review Board of the First Affiliated Hospital of Hunan University of Chinese Medicine

withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected. A final report should be submitted when the study is completely done or stopped prematurely.	
Review Frequency	12 months
Validity	1 year
Contact	Hong Zhao / Hua Wang +86 0731 85369233
Director	
IRB	Institutional Review Board of the First Affiliated Hospital of Hunan University of Chinese Medicine
Date	Jan 24, 2013

Institutional Review Board of the First Affiliated Hospital of Hunan University of Chinese Medicine

Sign-in Sheet of the Review Conference

Date: Jan 23, 2013

Review Committee Signature:

Name	Gender	Major	Signature
Zhihua Guo	Male	Chief Physician, Professor, Cardiovascular medicine, the first affiliated hospital of Hunan University of Chinese Medicine	
Juqiao He	Male	Chief Surgeon, Professor, Traditional Chinese Surgery, the first affiliated hospital of Hunan University of Chinese Medicine	
Yanling Zhao	Female	Chief Physician, Professor, the first affiliated hospital of Hunan University of Chinese Medicine	
Qihua Chen	Male	Chief Surgeon, Professor, Traditional Chinese Surgery, the first affiliated hospital of Hunan University of Chinese Medicine	
Mengjun Huang	Male	Chief Physician, Professor, Gastrointestinal Medicine, the first affiliated hospital of Hunan University of Chinese Medicine	
Yuejuan Zhang	Female	Chief Nurse, Professor, Nursing, the first affiliated hospital of Hunan University of Chinese Medicine	
Zhiguo Zhang	Male	Chief Pharmacist, Professor, Pharmacy, the first affiliated hospital of Hunan University of Chinese Medicine	
Jin Tan	Male	Chief Dentist, Professor, Integrated Chinese and Western Oral Medicine, the first affiliated hospital of Hunan University of Chinese Medicine	
Haibo Xie	Male	Assistant Chief Physician, Assistant Professor, Traditional Chinese Medicine, the first affiliated hospital of Hunan University of Chinese Medicine	
Xiaoping Guan	Male	Lawyer, Rongyuan Law Office	
Xiao Zhong	Female	Business Manager, Insurance, Tai Ping Life Hunan Branch Office	
Hong Zhao (secretary)	Female	Assistant Chief Nurse, Assistant Professor, Nursing, the first affiliated hospital of Hunan University of Chinese Medicine	

Attachment 8: Ethical approval of Hengyang Hospital affiliated to Hunan University of Chinese Medicine

湖南中医药大学附属衡阳医院伦理委员会文件（EC-AF-2013001）

伦理审查批件

项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随即对照试验		
项目编号	2013EC001	项目来源	“十二五”国家科技支撑计划
牵头单位	湖南中医药大学附属衡阳医院		
申办者（如有）			
主要研究者	岳增辉		
审查类别	初始审查	审查方式	会议审查
审查日期	2013.2.17	审查地点	医院门诊楼 11 楼会议室
审查委员	王诚喜、龙双才、邹岳萍、徐基平、钟新林、匡肇、董秋萍、贺新民、谢军、万贤明、谢春亮		
批准文件	研究方案：（VERSION1.020121105），知情同意书（V1.0）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》、国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 一个月提交研究报告；申报者应当向组长单位伦理委员会提交各中心的研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监察员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。		
有效期	2013 年 2 月 19~2014 年 2 月 18 日		
联系人及电话	谢军，0734-8137737		
主任委员签字			
湖南中医药大学附属衡阳医院伦理委员会（盖章） 2013 年 2 月 19 日			

共 1 页/第 1 页

版本号：1.00/版本日期：20130211

Institutional Review Board Documentation of Hengyang Hospital affiliated toHunan University of Chinese Medicine (EC_AF_2013001)

Ethics Review Approval

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Approval No.	2013EC001	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Clinical Site	Hengyang Hospital Affiliated to Hunan University of Chinese Medicine		
Applicant (if any)	/		
Site PI	Zenghui Yue		
ReviewAttribute	Initial Review	**ReviewMethods**	Meeting Review
Review Date	Feb 17, 2013	**Review Place**	Meeting Room, the 11th Floor of the Clinic Building of Yueyang Hospital
Review Committee	Chengxi Wang, Shuangcai Long, Yueping Zou, Jiping Xu, Xinlin Zhong, Zhao Kuang, Qiuping Dong, Xinmin He, Jun Xie, Xianming Wan, Chunliang Xie		
Approved Files	Study Protocol (VERSION 1.0_20121105), Informed Consent (V1.0)		
Review Comments	According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, Declaration of Helsinki, and "International ethical guidelines for biomedical research involving human subjects" made by Council for International Organizations of Medical Sciences, this clinical research was reviewed by the institutional review board (IRB) of Guang'anmen Hospital of China Academy of Chinese Medical Sciences. And the protocol and informed consent of this research were approved. Please conduct this clinical study following the GCP principles and the study protocol approved by our IRB. The health and rights of the subjects should be protected throughout the whole study. An application should be submitted if the change of the site PI, or any modification of the study protocol, informed consent, or the recruitment files are made. The report of the severe adverse events (SAE) should be submitted in time if any SAE or any other un-anticipated adverse event,which will affect the risk-reward ratio of this study, occurs. Researchers should submit the report of study progress before one month of the deadline according to the frequency of ethical review. A summary report of the study progressshould be submitted to the IRB of the leading center. In any condition which will greatly affect the progress of the study or increase the potential risk of the subjects, a written report should be submitted by the applicant to IRB. A protocol violation report should be submitted by the applicant/monitor/researcher in the following conditions: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly included		

Institutional Review Board Documentation of Hengyang Hospital affiliated toHunan University of Chinese Medicine (EC_AF_2013001)

	in the study; subjects do not withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected. A final report should be submitted when the study is completely done or stopped prematurely.
Validity Period	From Feb 19, 2013 to Feb 18, 2014
Contact	Jun Xie, +86 07348137737
Director Signature	
IRB of Hengyang Hospital Affiliated toHunan University of Chinese Medicine (Seal)	
Date: Feb 19, 2013	

Version No. 1.00 **/ Version Date:** 20130211

Attachment 9: Ethical approval of Hubei Provincial Hospital of TCM

伦理审查批件 AF/SC-08/04.3

湖北省中医院伦理委员会

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

伦理审查批件

Ethics Review Approval

批件号	HBZY2013-C007-01		
项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
申办者	中国中医科学院广安门医院		
研究单位	中国中医科学院广安门医院、北京中医药大学东直门医院、四川大学华西医院、中国中医科学院西苑医院、湖南中医药大学附属衡阳医院、湖南省中医院、上海中医药大学附属岳阳中西医结合医院、天津中医药大学第一附属医院、陕西省中医医院、江苏省中医院、山西中医学院中西医结合医院、湖北省中医院		
主要研究者	周仲瑜 主任医师		
审查类别	初始审查	审查方式	会议审查
审查日期	2013-01-23	审查地点	湖北省中医院伦理办会议室
审查委员	涂远超、文建华、刘建忠、郭艳红、费兰波、程业刚、王小琴、高文喜、周忠明、胡晓雪、石艳红、吴胜利		
批准文件	临床研究方案版本号/日期：VERSION1.0_20121106/2012-11-06； 受试者知情同意书版本号/日期：V1.0/2012-11-06。		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书开展该项研究。

请遵循GCP原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前1个月提交研究进展报告。

出现没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背GCP原则的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交结题报告。

跟踪审查频率	12个月
有效期	12个月
联系人与联系电话	张馨、陈学军 027-88920956
主任委员签字	涂远超
	湖北省中医院伦理委员会（盖章）
	日期：2013.1.30

第 1 页 共 1 页

湖北省中医院伦理委员会

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

会议签到表

Sign-in Sheet of Meeting

项目名称	①肾力欣颗粒Ⅱ期临床试验②红花黄色素注射液Ⅱb 期临床试验③ZONCARE-S9 型全数字彩超临床验证④灯盏丹芪胶囊Ⅲ期临床试验⑤臭氧综合治疗仪临床验证⑥连花急支片Ⅲ期临床试验⑦电针治疗女性尿失禁⑧扶阳罐疗法⑨龙牡壮骨颗粒临床试验
会议日期	2013 年 1 月 23 日

姓名	性别	专业背景	签名
涂远超	男	心血管内科	
巴元明	男	中医肾病	请假
刘建忠	男	中医儿科	
文建华	男	中医内科	
郭艳红	女	行政管理	
费兰波	女	中医针灸	
程业刚	男	中西医结合肾病	
王小琴	女	中医内科	
高文喜	男	中医外科	
周忠明	男	妇产科	
胡晓雪	女	药学	
吴胜利	男	律师	
石艳红	女	社区警务	石艳红
张 馨	女	中西医结合临床	
陈学军	男	科研管理	

Ethics Approval Documentation **AF/SC-08/04.3**

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

Ethics Review Approval

Approval No.	HBZY2013-C007-01		
Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Bidder	Guang'anmen Hospital of China Academy of Chinese Medical Sciences		
Clinical Sites	Guang'anmen Hospital of China Academy of Chinese Medical Sciences, Dongzhimen Hospital of Beijing University of Chinese Medicine, West China Hospital of Sichuan University, Xiyuan Hospital of China Academy of Chinese Medical Sciences, Hengyang Hospital of Hunan University of Chinese Medicine, the Second Affiliated Hospital of Hunan University of Chinese Medicine, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine of Shanghai University of Traditional Chinese Medicine, the First Affiliated Hospital of Tianjin University of Chinese Medicine, Shaanxi Province Hospital of TCM, Jiangsu Province Hospital of TCM, Shanxi Hospital of Integrated Chinese and Western Medicine, Hubei Province Hospital of TCM		
Site PI	Zhongyu Zhou, Chief physician		
Review Attribute	Initial Review	**Review Method**	Review Conference
Review Date	Jan 23, 2013	**Review Place**	IRB Conference Room
Review Committee	Yuanchao Tu, Jianhua Wen, Jianzhong Liu, Yanhong Guo, Lanbo Fei, Yegang Cheng, Xiaoqin Wang, Wenxi Gao, Zhongming Zhou, Xiaoxue Hu, Yanhong Shi, Shengli Wu		
Approved Files	Study Protocol: **Version No.** VERSION1.0_20121106, **Date:** Nov 6, 2012 Informed Consent: **Version No.** V1.0, **Date:** Nov 6, 2012		
Review Comments			
According to the "ethical review methods for biomedical study involving human subjects (trial)" (2007) issued by the Ministry of Health, the "Good Clinical Practice" (2003), "Provisions for Clinical Trials of Medical Device" (2004) issued by SFDA, WMA "Declaration of Helsinki", and CIOMS			

Ethics Approval Documentation **AF/SC-08/04.3**

"International ethical guidelines for biomedical research involving human subjects", through the review of this IRB, the study protocol and informed consent were approved to perform. Please conform to the GCP principle, and conform to the study protocol approved by this IRB. The health and rights of the subjects should be protected throughout the study. The study should be registered online before its start. An application should be submitted if any change of the site PI, or any modification of the study protocol, informed consent, or recruitment files are made. A severe adverse events (SAE) report should be submitted in time if any SAE occurs during the study. The researcher/applicant should submit the study progress report one month before the deadline in reference to the annual/periodical review frequency of our IRB. A report of protocol deviation should be submitted by the applicant/monitor/researcher when the following conditions occur: 1) conditions that violate the study protocol: subjects, who do not meet the inclusion criteria, or should be excluded according to the exclusion criteria, were included in the study; subjects do not withdraw from the study when he/she meets the rules of withdrawal; incorrect treatment or dose was given; prohibited combine medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected. A paused/terminated report should be submitted if the study is paused or terminated prematurely. A concluding report should be submitted if the study finished completely.	
Review Frequency	12 months
Validity Period	12 months
Contact	Xin Zhang / Xuejun Chen **Phone:** +86 027 88920956
Director Signature	Yuanchao Tu
	Ethics Committee of Hubei Province Hospital of TCM (Seal)
	Date: Jan 30, 2013

Ethics Approval Documentation **AF/SC-08/04.3**

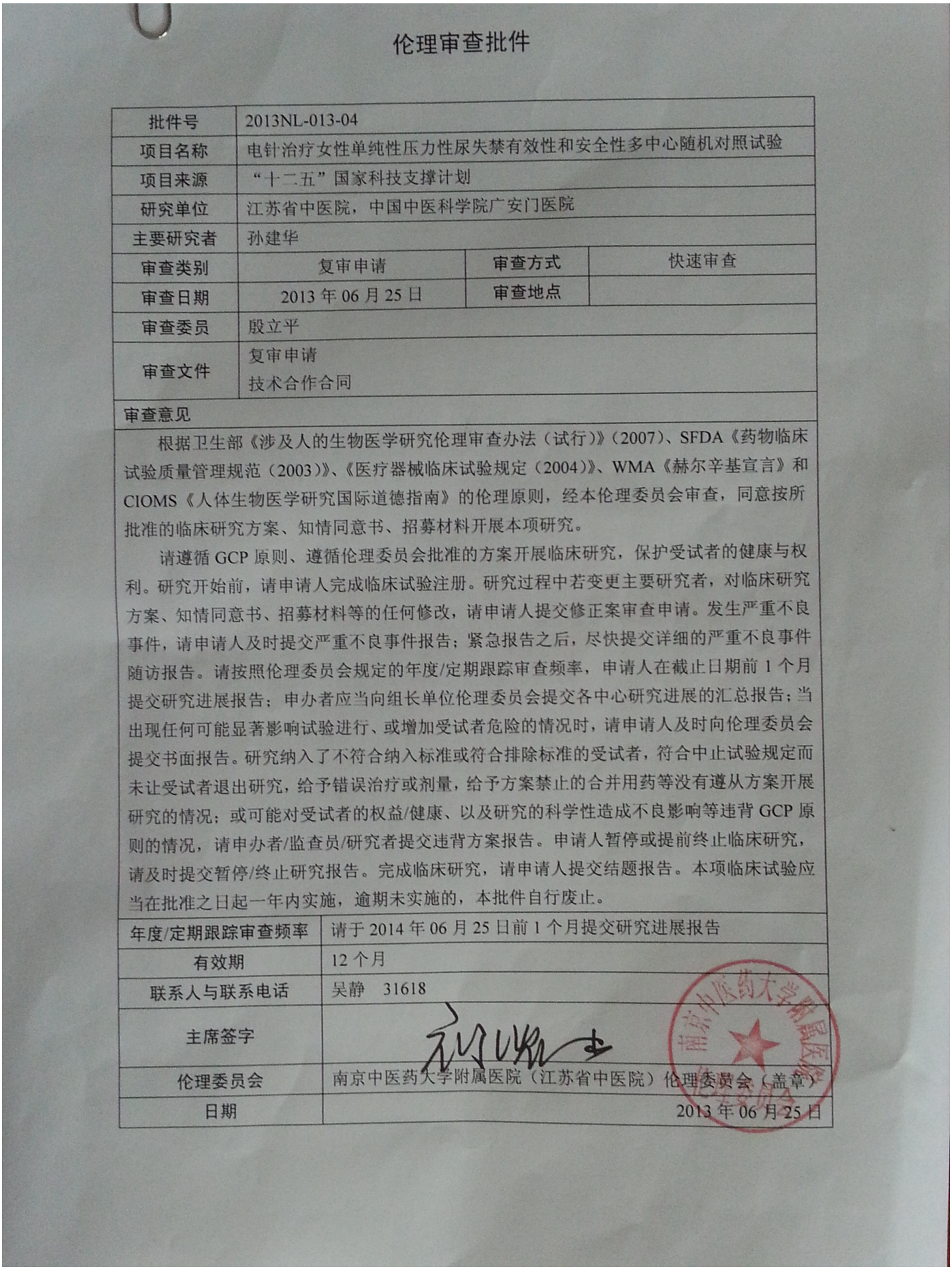
Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

Sign-in Sheet of Meeting

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial
Meeting Date	Jan 23, 2013

Name	**Gender**	**Major**	**Signature**
Yuanchao Tu	Male	Cadiovascular Medicine	
Yuanming Ba	Male	Nephropathy of TCM	
Jianzhong Liu	Male	Pediatrics of TCM	
Jianhua Wen	Male	Traditional Chinese Medicine	
Yanhong Guo	Female	Administration	
Lanbo Fei	Female	Acupuncture and Moxibustion	
Yegang Cheng	Male	Nephropathy of Integrated Chinese and Western Medicine	
Xiaoqin Wang	Female	Traditional Chinese Medicine	
Wenxi Gao	Male	Surgery of TCM	
Zhongming Zhou	Male	Gynaecology and Obstetrics	
Xiaoxue Hu	Female	Pharmacy	
Shengli Wu	Male	Lawyer	
Yanhong Shi	Female	Community Policing	
Xin Zhang	Female	Clinical Integrated Chinese and Western Medicine	
Xuejun Chen	Male	Scientific Research Management	

Attachment 10: Ethical approval of Jiangsu Province Hospital of TCM



伦理审查批件

批件号	2013NL-013-04		
项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
项目来源	“十二五”国家科技支撑计划		
研究单位	江苏省中医院，中国中医科学院广安门医院		
主要研究者	孙建华		
审查类别	复审申请	审查方式	快速审查
审查日期	2013 年 06 月 25 日	审查地点	
审查委员	殷立平		
审查文件	复审申请 技术合作合同		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究开始前，请申请人完成临床试验注册。研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。发生严重不良事件，请申请人及时提交严重不良事件报告；紧急报告之后，尽快提交详细的严重不良事件随访报告。请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。完成临床研究，请申请人提交结题报告。本项临床试验应当在批准之日起一年内实施，逾期未实施的，本批件自行废止。

年度/定期跟踪审查频率	请于 2014 年 06 月 25 日前 1 个月提交研究进展报告
有效期	12 个月
联系人与联系电话	吴静　31618
主席签字	
伦理委员会	南京中医药大学附属医院（江苏省中医院）伦理委员会（盖章）
日期	2013 年 06 月 25 日

Institutional Review Board of Jiangsu Province Hospital of Traditional Chinese Medicine

Ethics Review Approval

Approval No.	2013NL-013-04		
Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Project Sponsor	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China		
Clinical Site	Jiangsu Province Hospital of TCM, Guang'anmen Hospital		
Site PI	Jianhua Sun		
Review Attribute	Review Application	**Review Method**	Fast Review
Review Date	Jun 25, 2013	**Review Place**	
Review Commissioner	Liping Yin		
Approved Files	Review Application Technological Cooperation Contract		
Review Comments			
According to the principles of the "ethical review methods for biomedical study involving human subjects (trial)" (2007) issued by the Ministry of Health, SFDA "Good Clinical Practice" (2003), SFDA "Provisions for Clinical Trials of Medical Device" (2004), WMA "Declaration of Helsinki" and CIOMS "international ethical guidelines for biomedical research involving human subjects", through the review of our IRB, the study protocol, informed consent, and the recruitment files were approved. Please conform to the principle of the GCP, and the study protocol approved by this IRB. Please protect the health and rights of the subjects. This clinical trial should be registered online by the applicant/PI before its start. A revision review application should be submitted if any modification of the protocol, informed consent, or recruitment files, or a change of the site PI were made. A severe adverse event (SAE) report should submitted in time if any SAE occurs, and a follow-up SAE report should also be submitted in time after that. The report of the study progress should be submitted one month before the deadline according to the review frequency. Summary report should be submitted by the applicant/site PI to the IRB of the leading site. If any condition that will influence the progress of the study or increase the risk of the subjects occurs, a written report should be submitted to the IRB by the applicant/site PI. A protocol deviation report should be submitted by the applicant/monitor/researcher in the following conditions: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly included in the study; subjects do not withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected. The applicant or researcher should submit the paused/terminated report if the study is paused or terminated prematurely. A conclusion report should be handed in if the study is finished completely. The study should be performed within one year after this approval; otherwise, this approval will be abolished.		
Review Frequency	Please submit the study progress report 1 month before Jun 25, 2014		
Validity	12 Months		
Contact	Jing Wu **Phone:** +86 025 86617141-31618		

Institutional Review Board of Jiangsu Province Hospital of Traditional Chinese Medicine

Director Signature	
Institutional Review Board	Institutional Review Board of Jiangsu Province Hospital of TCM (the Affiliated Hospital of Nanjing University of Chinese Medicine) (SEAL)
Date	Jun 25, 2013

Attachment 11: Ethical approval of Shanxi Province Hospital of TCM

陕西省中医医院伦理委员会

临床研究伦理审查批件

（2013）伦审第（02）号

项目名称	针灸疗效国际多中心临床评价研究 (电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验)				
申请单位	陕西省中医医院针灸科				
项目来源	“十二五”国家科技支撑计划	批准文号	课题编号：2012BAI24B01		
承担研究任务科室	针灸科	主要研究者	苏同生	职称	主任医师
会议时间	2013 年 02 月 01 日	会议地点	院会议室	审查方式	会议审查
审查文件	1、临床研究方案（版本号：VERSION1.0_20121106）； 2、例报告表(版本号:VERSION1.0_201201109)； 3、知情同意书； 4、研究者专业履历及专业科室人员配备、设备设施情况； 5、研究者手册；　有□　无■ 6、其他伦理委员会对本研究项目的决定；　有■　无□				
审查内容	研究者的资格：　符合要求■　不符合要求□ 人员配备：　符合要求■　不符合要求□ 设备条件：　符合要求■　不符合要求□ 知情同意书：　符合要求■　不符合要求□ 获取知情同意书的方法：恰当■　不恰当□ 研究方案：　符合要求■　不符合要求□ 受试者因参加临床试验　有有效抢救措施■　无有效抢救措施□ 发生不良反应或意外：　有补偿规定■　无补偿规定□				
审查意见	同意	作必要的修改后同意	作必要的修正后重审	不同意	终止或暂停已批准的研究
	3 人	5	0	0	0
出席人数	应到：9 人	实到：9 人	回避：1 人(投票时)	请假：0 人	
审批意见：经审查该项目临床试验方案符合要求,请对知情同意书进行修改，具体为：在“知情同意书.知情告知页”中明确告知受试者，对照组为“安慰对照治疗”。做出上述修改后，同意开展临床研究。					
主任委员签字： 日期：2013 年 2 月 1 日	会议记录者签字： 日期：2013 年 2 月 1 日		联系电话：029-87251691		

Institutional Review Board of Shaanxi Province of Traditional Chinese Medicine

Ethics Review Approval

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial				
Applicant Site	Acupuncture and Moxibustion Department, Shanxi Province Hospital of TCM				
Project Sponsor	National Key Technology R&D Program during the Twelfth Five-year Plan Period of China			**Project No.**	2012BAI24B01
Department	Acupuncture and Moxibustion Department	**Site PI**	Tongsheng Su	**Title**	Chief Physician
Meeting Date	Feb 1, 2013	**Meeting Place**	Conference Room of the Hospital	**Review Type**	Meeting Revies
Review Files	1. study protocol (VERSION1.0_20121106); 2. Case Report Form (VERSION1.0_20121109); 3. Informed Consent; 4. Researchers' CV, Personnel Allocation, Equipment and Facility; 5. Researchers' Handbook Yes ☐ No ■ 6. Decision by Other IRB Yes■ No ☐				
Review Contents	Researchers' Qualification: Meet Requirement ■ Not Meet Requirement ☐ Personnel Allocation: Meet Requirement ■ Not Meet Requirement ☐ Equipment and Facility: Meet Requirement ■ Not Meet Requirement ☐ Informed Consent: Meet Requirement ■ Not Meet Requirement ☐ Informed Consent Obtained: Appropriate ■ Not Appropriate ☐ Study Protocol Meet Requirement ■ Not Meet Requirement ☐ Subjects' AE or Accident: With Effective Emergency Measures ■ Without Effective Emergency Measures ☐ With Compensation ■ Without Compensation ☐				

Review Comments	approved	approved after revision	review after revision	not approved	Terminated/Paused
	3	5	0	0	0

Institutional Review Board of Shaanxi Province of Traditional Chinese Medicine

Attendance People	Anticipated: 9	Participated: 9	Avoided: 1	Left: 0
Approval Comments: The study protocol of this trial conforms to the requirements, but the informed consent needs to be revised. Subjects should be informed that the control group uses plocebo treatment. The study will be approved after revision.				
Director Signature: Guangyang Wei **Date:** Feb 1, 2013		**Meeting Recorder:** Yifei Zhao **Date:** Feb 1, 2013		**Telephone:** +86 029 87251691

Attachment 12: Ethical approval of Shanxi Hospital of Integrated Traditional and Western Medicine

伦理审查批件

项目名称	电针治疗女性单纯性压力性尿失禁有效性和安全性多中心随机对照试验		
项目编号	2012EC007	项目来源	“十二五”国家科技支撑计划
牵头单位	中国中医科学院广安门医院		
申办者（如有）	山西中医学院中西医结合医院		
主要研究者	王杰 高素云 赵文兵		
审查类别	初始审查	审查方式	会议审查
审查日期	2013.2.25	审查地点	医院五楼会议室
审查委员	樊东升，王毅东，高继宁，蔺涛，刘红玲，田成瑛，闫荔		
批准文件	研究方案（VERSION1.0_20121106）,知情同意书(V1.0)		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（执行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛集宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险收益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的粘度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；定期向牵头单位伦理委员会提交研究进展的汇总报告。 提前终止或完成临床研究，请及时提交结题报告。		
有效期	2013 年 3 月 1 日——2014 年 2 月 28 日		
联系人与联系电话	蔺涛 0351-2621527		
主任委员签字			
	山西中医学院中西医结合医院伦理委员会（医务科代章）		
	日期：2013 年 02 月 25 日		

Institutional Review Board of Shanxi Hospital of Integrated Traditional and Western Medicine

Ethics review Approval

Project Title	The Effect and Safety of Electro-acupuncture for Women with Pure Stress Urinary Incontinence: a Multicenter, Randomized Controlled Trial		
Approval No.	2012EC007	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Leading Organization	Guang'anmen Hospital of China Academy of Chinese Medical Sciences		
Applicant (if any)	Shanxi Hospital of Integrated Traditional and Western Medicine		
Site PI	Jie Wang, Suyun Gao, Wenbing Zhao		
Review Attribute	Initial Review	**Review Methods**	Review conference
Review data	Feb 25, 2013	**Review Place**	Conference Room, the 5th Floor of the Administrative Building of the Hospital
Review Committee	Dongsheng Fan, Yidong Wang, Jining Gao, Tao Lin, Hongling Liu, Chengying Tian, Li Yan		
Approved Files	Study Protocol (VERSION 1.0_20121106), Informed Consent (V1.0)		
Review Comments	According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, Declaration of Helsinki, and "International ethical guidelines for biomedical research involving human subjects" made by Council for International Organizations of Medical Sciences, through the review of this IRB, the study protocol, informed consent, and recruitment files of this research were approved. Please conduct this clinical study following the GCP principles and the study protocol approved by IRB. The health and rights of the subjects should be protected throughout the whole study.		

Institutional Review Board of Shanxi Hospital of Integrated Traditional and Western Medicine

	An application should be submitted if there are major revisions in principle investigator, study protocol, informed consent, or the recruitment files. A report of the severe adverse events (SAE) should be submitted in time if any SAE or any other un-anticipated adverse event, which will affect the risk-reward ratio of this study, occurs. Researchers should submit report of the study progress one month before the deadline according to the ethical review frequency. A summary report of the study progress should be submitted to the IRB of the leading site. A final report should be submitted when the study is completely done or stopped prematurely.
Validity period	From Mar 1, 2013 to Feb 28, 2014
Contact and Phone	Tao Lin +86 0351 2621527
Director Signature	Dongsheng Fan
IRB of Shanxi Hospital of Integrated Traditional and Western Medicine (SEAL)	
Date: Feb 25, 2013	

Institutional Review Board Documentation of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (EC_AF_031)

Ethics Approval of Guang'anmen Hospital of China Academy of Chinese Medical Sciences

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	2013EC125-01	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Research Unit	Guang'anmen Hospital, China Academy of Chinese Medical Sciences; West China Hospital of Sichuan University; Shaanxi Province Hospital of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; Yantai Hospital of Traditional Chinese Medicine; The First Hospital of Hunan University of Chinese Medicine; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; Hubei Provincial Hospital of Traditional Chinese Medicine; Qingdao Haici Medical Center		
Major researcher	Zhishun Liu	**Department of the researchers**	Department of Acupuncture
Review attribute	Re-review	**Review method**	Expedited Review
Review Date	2014-01-16	**Review Place**	The Meeting Room
Name of Review members	Xinghua Feng, Jun Zhao		
Approval Documents	1. Study protocol (Version 2.0_20140102) 2. Consent (Version 2.0) 3. Case Report Form (Version 2.0_20140102) 4. Recruitment advertisement (Version 2.0_20140102) 5. Researcher Handbook (Version 2.0_20140102) 6. bladder diary (Version 1.0_20131218)		
Reviewers' Comments:	According to the 'Ethical Review of Biomedical Research Related to Human' formulated by Ministry of Public Health, 'Specifications for the quality control of drugs used in clinical trials in China Academy of Chinese Medical Sciences' formulated by State food and drug administration, 'The Provisions for Medical Device Classification', 'Guidelines for ethical review of clinical trials related to drugs', 'Standard for clinical research on ethical review and management of TCM clinical research' formulated by State Administration of Traditional Chinese Medicine(under the Ministry of Public Health), 'Declaration of Helsinki', 'International Moral Guide for biomedical research' formulated by Council for International Organizations of Medical Sciences, all the reviewers approved the conduction of this study. Please follow the principle of GCP and protocol of this study approved by the review boards and ethics committees and protect the rights of participants during the process of this study.		

	If the starting time of the study is later than validity date of the ethical document, the ethical approval will be invalid and researchers should resubmit an application for ethical approval. If the major researcher have been altered or any amendments in the protocol, informed consent and recruitment advertisement have been made, the researchers should resubmit an application for ethical approval. If there are any severe adverse events or adverse events affecting the benefit of the research, the researchers should submit the report of adverse events in 15 days and submit the report of adverse events which cause death in 7 days. Researchers should submit report of progress of the study before one month of the deadline according to frequency of ethical review. Researchers should submit summary reports about circumstances severely affecting the ongoing of the study and increasing the risk of participants in time to review boards and ethics committees. If the following circumstances happen in the whole process of this study, applicants/researchers/ inspectors should submit a report about reasons causing the violation of study design: 1. Participants who met the inclusion criteria. 2. Participants who met the provisions of termination but weren't terminated. 3. Participants who were given incorrect therapy or wrong doses of medication. 4. Participants who had taken forbidden combined medication according to the design of the study. 5. Any conditions which violating the principle of GCP and affecting the participants' rights/health or the scientific nature of the study. Please submit a report in time when the study is finished or terminated in advance.
Period of validity of this ethical approval document	From 2014-01-18 to 2015-01-17
Contact	**Name:** Jie Qiao
	Phone: 86-010-88001552
Signature of Chairman of the review boards and ethics committees	

中国中医科学院广安门医院伦理委员会文件（EC_AF_031）

伦理审查批件

项目名称	隔针和 PEMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验		
批件号	2013EC125-01	项目来源	国家级课题
研究单位	中国中医科学院广安门医院，北京中医药大学东直门医院，四川大学华西医院，天津中医药大学第一附属医院，湖南中医药大学附属衡阳医院，湖南中医药大学第一附属医院，湖北省中医院，江苏省中医院，陕西省中医院，青岛市海慈医疗集团		
申办者	无		
主要研究者	刘志顺	研究科室	针灸科
审查类别	复审	审查方式	快速审查
审查日期	2014-1-16	审查地点	中国中医科学院广安门医院
审查委员	冯兴华，赵军		
批准文件及版本	研究方案（VERSION 2.0_20140102），知情同意书（VERSION 2.0），病例报告表（VERSION 2.0_20140102），招募广告（VERSION 2.0_20140102），研究者手册（VERSION 2.0_20140102），排尿日记卡（VERSION 1.0_20131218）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 若在本批件有效期内未启动研究，本批件作废，需重新提交伦理审查申请。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科		

	学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。
有效期	2014 年 1 月 18 日～2015 年 1 月 17 日
联系人与联系电话	乔洁 010-88001552
主任委员签字	
中国中医科学院广安门医院伦理委员会（盖章）	
日期：2014 年 1 月 17 日	

Institutional Review Board Documentation of Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine

Approval Notice Template

Accepted No. ECSL-BDY-2014-05 Approval No. ECPJ-BDY-2014-05

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Research Center	Dongzhimen Hospital		
Set PI	Jiping Zhao	Project Attribute	The National Key Technology Support Program
Review method	Expedited Review		
member	Anticipated 14, participated 11, avoiding 0, absented 3		
Approval Documents	1. Study protocol (1.0_20140102), approval date: Jan. 2014 2. Consent (Version 2.0), approval date: Jan. 2014		

According to the "Guidelines for Ethical Review Work of Drug Clinical Trials" (2010), the "Good Clinical Practice" (2003), the "Guiding Principle of Herb Variety Protection" (2009) issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Declaration of Helsinki" (2008), the "ethical review methods for biomedical study involving human subjects" (2007) issued by the Ministry of Health, the "Management specifications for ethical review of TCM clinical studies" (2010) issued by State Administration of Traditional Chinese Medicine, and the "International ethical guidelines for biomedical research involving human subjects" (2002) issued by Council for International Organizations of Medical Sciences, our IRB agreed that:

√ approved

□ not approved

□ terminated

□ paused

Review Comments	**APPROVED** Note: The validity of this approval is 1 year. Site PI must abide by the approved documents. If the trial could not accomplish before the validity (including the statistical analysis), please submit for continuing review 1 month before the deadline. If the trial accomplished in the validity, please submit the final report. If there is any adverse event related to the trial occurred, please reported to the committee. If there is any change about the protocol, informed consent, or investigators, modification application must be submitted to the committee and get approved.

Director √ Assistant director □ Signature: Date: Jan 25. 2014

Institutional Review Board of Dongzhimen Hospital Affiliated to BUCM Place: the 1st meeting room

Continuing Review Frequency □ 3 mon □ 6 mon √ 12 mon Contact: Jianwei Shang +86 010 84013229

北京中医药大学东直门医院医学伦理委员会
IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

伦理审查批件

Approval Notice Template

受理序号：ECSL-BDY-2014-05　　批件号：ECPJ-BDY-2014-05

项目名称：电针和 PFMT 联合索利那新治疗女性中重度混合型尿失禁的疗效比较：多中心随机对照非劣性试验

申办单位：北京中医药大学东直门医院	主要研究者：赵吉平
项目类别：科研课题	批文号/课题编号：2012BAI24B01
方案版本号：VERSION2.0_20140102	方案批准日期： 2014.01
知情同意书版本号：VERSION2.0	知情同意书批准日期：2014.01

伦理审查方式： ☒会议审查　☐快速审查

应到会 14 人，出席本次会议人员 11 人，回避 0 人，缺席 3 人

根据中华人民共和国国家食品药品监督管理局（CFDA）《药物临床试验伦理审查工作指导原则》（2010 年）、《药物临床试验质量管理规范》（2003）、《中药品种保护指导原则》（2009），世界医学会《赫尔辛基宣言》（2008），卫生部《涉及人的生物医学研究伦理审查办法》（2007），国家中医药管理局《中医药临床研究伦理审查管理规范》（2010）以及国际医学科学组织委员会《人体生物医学研究国际道德指南》（2002）的伦理原则，经本伦理委员会审查决定：	☒同意临床研究方案 ☐不同意临床研究方案 ☐终止临床研究方案 ☐暂停临床研究方案

审查意见：

同意临床试验

注：本批件自签发日期有效期四年，研究负责人必须严格使用经审查同意的知情同意书文本和研究方案。如伦理审查批件失效时不能完成所有的临床研究（包括统计分析），请在本批件失效前一个月，递交持续审查申请。如研究结束并在审查有效期内，请递交研究结题报告。研究中发生涉及受试者或其他人风险的任何预期或非预期的不良事件，应立刻报告本伦理委员会；任何研究方案、知情同意书的修改包括研究人员的变更，必须递交研究方案修改申请表，经伦理委员会审查获得批准后执行。

主任委员☐副主任委员☐签字：　　时 间：2014年 1 月25日

北京中医药大学东直门医院医学伦理委员会　　地 点： 第一会议室

本项目持续审查频率：☐ 6 个月 ☒ 12 个月　联系人：商建伟 （010）84013229

北京中医药大学东直门医院医学伦理委员会

IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

会议签到表

Meeting attendance sheet

项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合型尿失禁的疗效比较：多中心随机对照非劣效性试验		
会议时间	2014.1.24	会议地点	第一会议室

成员	性别	伦理委员会职务	专业背景	签名
叶永安	男	主任	中医内科学	
高　颖	女	副主任	中医内科学	
柳红芳	女	副主任	中西医结合	
田金洲	男	委员	管　理	
张永涛	男	委员	西医内科学	
杨博华	男	委员	中医外科学	
鲁卫星	男	委员	院外代表	
王蓬文	女	委员	药理学	
曹俊岭	男	委员	药剂科	
赵波	男	委员	法律代表	
贺海东	男	委员	医疗器械	
孟歌红	女	委员	群众代表	
陈信义	男	委员	中医内科学	
彭淑莲	女	委员	中医外科学	

医学伦理委员会专用章

Institutional Review Board of West China Hospital of Sichuan University

Ethics Review Approvals

Approval No. 2014-7

Title of the project	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Medication: Solifenacin Succinate		Form: pill Specification: 5mg	
Has this medication been included in the hospital's pharmacy: √ No □ Yes			
Major researcher	Ning Li Associate Chief Physician	**Research Department**	Department of Integrated Medicine
Sponsor (Funder)	Guang'anmen Hospital		
Method of the ethical review of this study	√ Meeting review □ quick review		
Place of the ethical review	413 meeting room		

Review Comments:

1. The Site PI selected met the requirements of ethics.
2. The study protocol and informed consent met the requirements of ethics.

Review Result: ■ approved ☐ approved after revision ☐ reviewed again after revision ☐ not approved ☐terminated or suspended

Researchers must obey the related laws and regulations such as SFDA "Good Clinical Practice (2003)", "Provisions for Clinical Trials of Medical Device (2004)", WMA "Declaration of Helsinki", CIOMS "International ethical guidelines for biomedical research involving human subjects (2007)". The study should perform according to the protocol and informed consent approved by this IRB. The health and right of the subjects should be protected.

If a change of the Site PI, or any modification of the protocol/informed consent was made, a new ethics approval application of the modified files must be submitted.

Researchers should report the severe adverse event (SAE) in time if any SAE occurred during the study. After the report, a detailed follow-up report of the SAE should also be submitted in time.

Please submit the annual or regular follow-up review report in time. In any condition which will greatly affect the progress of the study or increase the risk of the subjects, a written report should be submitted to the IRB.

The applicant/monitor/researcher should submit a protocol deviation report if any of the following condition occurs: 1) subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly included in the study; 2) subjects do not withdraw from the study when he/she meet the rules of withdrawal; 3) incorrect treatment or dose was given; 4) prohibited combined medicine was used; 5) subjects' rights and health are badly affected; 6) the science of study was badly affected.

A concluding report should be submitted when the study is completely done or stopped prematurely.

IRB of West China Hospital of Sichuan University

Director Signature:

Date: Apr 10, 2014

四川大学华西医院临床试验与生物医学伦理专委会审查批件

2014年临床试验（上市）审（7）号

科室（专业）： 中西医结合科	研究负责人： 李宁 副主任医师
药品：琥珀酸索利那新片	剂型：片剂 规格：5mg
药品是否已进入本院药库： 是□ 否■	
药品临床研究名称：电针和PFMT联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验	
申办者（或基金资助者）：中国中医科学院广安门医院	
审查方式： ■会议审查 □快速审查	
审查会议地点：四川大学华西医院老八教413会议室	

评审意见：

1.研究者资质符合伦理要求。

2.研究方案及知情同意书基本符合伦理要求。

3.请严格按照临床规范和药品使用说明书实施电针和药物研究。

审查结果：■同意 □作必要修正后同意 □作必要修正后再审 □不同意 □终止或暂停

持续审查频率：□3 个月/3months □6 个月/6months ■1 年/1year □不适用/NA

请遵循我国相关法律、法规和规章（SFDA《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定》（2004）、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》、卫生部《涉及人的生物医学研究伦理审查办法（试行）（2007）》），遵循伦理委员会批准的方案和知情同意书开展临床试验（研究），保护受试者的健康与权利。

在试验（研究）过程中，若变更主要研究者，对临床研究方案、知情同意书等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告；紧急报告之后，尽快提交详细的严重不良事件随访报告。

请递交年度和定期跟踪审查报告；当出现任何可能显著影响试验（研究）进行或增加受试者危险的情况时，请申请人及时向伦理专委会提交书面报告。

试验（研究）纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验（研究）规定而未让受试者退出试验（研究），给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背伦理原则与规范的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床试验（研究），请及时提交暂停/终止试验（研究）报告。

完成临床试验（研究），请申请人提交结题报告。

本批件有效期为一年，逾期未实施的，则自行废止。

单 位（章）：

主任委员（签名）：

日期：2014年4月10日

联系方式：成都市武侯区国学巷37号四川大学华西医院老八教412，孙荣国/左泽锦/李娜 电话/传真：028-85422654

（附件见背面）

Sun B, *et al*. *BMJ Support Palliat Care* 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

四川大学华西医院临床试验与生物医学伦理专委会会议参会委员名单

姓名	性别	专业	职称	工作单位	签字	日期
曾勇（主任委员）	男	肝胆胰外科	教授	四川大学华西医院		2014.4.8.
孙荣国	男	医学管理	教授	四川大学华西医院		2014.4.8.
毛兵	男	中西医结合科	教授	四川大学华西医院		2014.4.8.
刘晓雪	女	烧伤整形科	教授	四川大学华西医院		
张瑞明	女	中西医结合科	教授	四川大学华西医院		
郑鸿	男	肿瘤科	教授	四川大学华西医院		
兰礼吉	男	伦理学	教授	四川大学政治学院		2014.4.8
傅政勇	男	法律学	律师	中豪律师集团（四川）事务所		2014.4.8.
赵建芳	女	教育学	教师	成都市武侯计算机实验小学		2014.4.8

Institutional Review Board Documentation of Yantai Hospital of Traditional Chinese Medicine

Ethics Review Approval

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	2013EC125-01	Project Sponsor	The National Key Technology Support Program
Research Unit	Yantai Hospital of Traditional Chinese Medicine		
Major researcher	Zhiwei Zang	**Department of the researchers**	Department of Acupuncture
Review Type	Re-review	**Review Method**	Expedited Review
Review Date	2014-02-20	**Review Place**	Yantai Hospital of Traditional Chinese Medicine
Name of Review members	Xian Dong, Guiping Xu		
Approval Documents	Study Protocol (Version 2.0_20140102), Consent (Version 2.0), Case Report Form (Version 2.0_20140102), Recruitment Advertisement (Version 2.0_20140102), Researcher Handbook (Version 2.0_20140102), Bladder Diary (Version 1.0_20131218)		
Reviewers' Comments:	According to the 'Ethical Review of Biomedical Research Related to Human' formulated by Ministry of Public Health, 'Specifications for the quality control of drugs used in clinical trials in China Academy of Chinese Medical Sciences' formulated by State food and drug administration, 'The Provisions for Medical Device Classification', 'Guidelines for ethical review of clinical trials related to drugs', 'Standard for clinical research on ethical review and management of TCM clinical research' formulated by State Administration of Traditional Chinese Medicine(under the Ministry of Public Health), 'Declaration of Helsinki', 'International Moral Guide for biomedical research' formulated by Council for International Organizations of Medical Sciences, all the reviewers approved the conduction of this study. Please follow the principle of GCP and protocol of this study approved by the review boards and ethics committees and protect the rights of participants during the process of this study. If the starting time of the study is later than validity date of the ethical document, the ethical approval will be invalid and researchers should resubmit an application for ethical approval. If the major researcher have been altered or any amendments in the protocol, informed consent and recruitment advertisement have been made, the researchers should resubmit an application for ethical approval. If there are any severe adverse events or adverse events affecting the benefit of the research, the researchers should submit the report of adverse events in 15 days and submit the report of adverse events which cause death in 7 days. Researchers should submit report of progress of the study before one month of the deadline according to frequency of ethical review. Researchers should submit		

	summary reports about circumstances severely affecting the ongoing of the study and increasing the risk of participants in time to review boards and ethics committees. If the following circumstances happen in the whole process of this study, applicants/researchers/ inspectors should submit a report about reasons causing the violation of study design: 1. Participants who met the inclusion criteria. 2. Participants who met the provisions of termination but weren't terminated. 3. Participants who were given incorrect therapy or wrong doses of medication. 4. Participants who had taken forbidden combined medication according to the design of the study. 5. Any conditions which violating the principle of GCP and affecting the participants' rights/health or the scientific nature of the study. Please submit a report in time when the study is finished or terminated in advance.
Period of validity of this ethical approval document	From 2014-02-20 to 2015-02-29
Contact	Jinghua Ma, Tel. +86-0535-2127022
Signature of Chairman of the review boards and ethics committees	

烟台市中医医院伦理审查批件

项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验		
批件号	2013EC125-01	项目来源	国家级课题
研究单位	中国中医科学院广安门医院，北京中医药大学东直门医院，四川大学华西医院，烟台市中医医院，湖南中医药大学附属衡阳医院，湖南中医药大学第一附属医院，湖北省中医院，江苏省中医院，陕西省中医院，青岛市海慈医疗集团		
申办者（如有）	无		
主要研究者	臧志伟	研究科室	针推科
审查类别	复审	审查方式	快速审查
审查日期	2014-2-20	审查地点	烟台市中医医院
审查委员	董锡安 徐桂萍		
批准文件及版本	研究方案（VERSION2.0__20140102），知情同意书（VERSION 2.0）病例报告表（VERSION 2.0__20140102），招募广告（VERSION 2.0__20140102），研究者手册（VERSION 2.0__20140102），排尿日记卡（VERSION 1.0__20131218）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 若在本批件有效期内未启动研究，本批件作废，需重新提交伦理审查申请。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度／定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试		

	者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益／健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者／监查员／研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。
有效期	2014 年 2 月 20 日～2015 年 2 月 19 日
联系人与联系电话	马静华 0535-2127022
主任委员签字	
	烟台市中医医院伦理委员会（盖章） 日期：2014 年 2 月 20 日

Institutional Review Board Documentation of Hengyang Hospital affiliated to Hunan University of Chinese Medicine (EC_AF_2014001)

Ethics Review Approval

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	2012BA124B01	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program
Research Unit	Hengyang Hospital affiliated to Hunan University of Chinese Medicine		
Major researcher	Zenghui Yue	**Department of the researchers**	Department of Acupuncture
Review Type	Initial Review	**Review Method**	Meeting Review
Review Date	2014-01-06	**Review Place**	Meeting room, the 11th floor of the clinic building of Yueyang Hospital
Name of Review members	Chengxi Wang, Shuangcai Long, Yueping Zou, Jiping Xu, Xinling Zhong, Zhao Kuang, Qiuping Dong		
Approval Documents	1. Study protocol (Version 2.0_20140102) 2. Consent (Version 2.0_20140102)		
Reviewers' Comments:	According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese Medicine, Declaration of Helsinki, and "International ethical guidelines for biomedical research involving human subjects" made by Council for International Organizations of Medical Sciences, this clinical research was reviewed by the institutional review board (IRB) of Guang'anmen Hospital of China Academy of Chinese Medical Sciences. And the protocol and informed consent of this research were approved. Please conduct this clinical study following the GCP principles and the study protocol approved by our IRB. The health and rights of the subjects should be protected throughout the whole study. An application should be submitted if the change of the site PI, or any modification of the study protocol, informed consent, or the recruitment files are made. The report of the severe adverse events (SAE) should be submitted in time if any SAE or any other un-anticipated adverse event,which will affect the risk-reward ratio of this study occurs. Researchers should submit the report of study progress before one month of the deadline according to the frequency of ethical review. A summary report of the study progressshould be submitted to the IRB of the leading center. In any condition which will greatly affect the progress of the study or increase the potential risk of the subjects, a written report should be submitted by the applicant to IRB. A protocol violation report should be submitted by the applicant/monitor/researcher in the following conditions: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly includedin the study; subjects do not withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected.		

	A final report should be submitted when the study is completely done or stopped prematurely.
Period of validity of this ethical approval document	From 2014-03-01 to 2015-09-30
Frequency of ethical review	Jun Xie, Tel. +86-0734-8137737
Signature of Chairman of the review boards and ethics committees	

湖南中医药大学附属衡阳医院伦理委员会文件（EC-AF-2014001）

伦理审查批件

项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的比较研究：多中心随机对照非劣效性试验		
项目编号	2012BAI24B01	项目来源	“十二五”国家科技支撑计划
牵头单位	湖南中医药大学附属衡阳医院		
申办者（如有）			
主要研究者	岳增辉		
审查类别	初始审查	审查方式	快速审查
审查日期	2014.01.06	审查地点	医院门诊楼 9 楼会议室
审查委员	王诚喜、龙双才、邹岳萍、徐基平、钟新林、匡肇、董秋萍		
批准文件	研究方案：（版本号：VERSION 2.0_20140102） 知情同意书[版本号：VERSION 2.0_20140102）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》、国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申报者应当向组长单位伦理委员会提交各中心的研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监察员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。		
有效期	2014 年 3 月 1 日~2015 年 9 月 30 日		
联系人及电话	谢军，0734-8137737		
主任委员签字			
	湖南中医药大学附属衡阳医院伦理委员会（盖章）		
	2014 年 1 月 6 日		

共 1 页/第 1 页

版本号：1.00/版本　日期：20140106

Institutional Review Board Documentation of the First Affiliated Hospital of Hunan University of Chinese Medicine

No. AF/SC-08/01.0

Ethics Review Approval

Project Title	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Accepted No.	HN-LL-KY-2013-001-01		
Project Sponsor	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China		
Research Unit	the First Affiliated Hospital of Hunan University of Chinese Medicine		
Site PI	Wei Zhang		
Review Attribute	Initial Review	**Review Placebo**	Meeting Review
Review Date	2014-01-16	**Review Place**	Meeting Room of the Hospital
Name of Review members	Zhihua Guo, Juqiao He, Yanling Zhao, Qihua Chen, Mengjun Huang, Zhiguo Zhang, Danjuan Zhang, Jin Tan, Xiao Zhong		
Approval Documents	1. Study protocol (Version 2.0_20140102) 2. Consent (Version 2.0)		

Review Comments

According to "ethical review methods for biomedical study involving human subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "management specifications for ethical review of TCM clinical studies" issued by State Administration of Traditional Chinese

Medicine, Declaration of Helsinki, and "International ethical guidelines for biomedical research involving human subjects" made by Council for International Organizations of Medical Sciences, this clinical research was reviewed by the institutional review board (IRB) of Guang'anmen Hospital of China Academy of Chinese Medical Sciences. And the protocol and informed consent of this research were approved.

Please conduct this clinical study following the GCP principles and the study protocol approved by our IRB. The health and rights of the subjects should be protected throughout the whole study.

An application should be submitted if the change of the site PI, or any modification of the study protocol, informed consent, or the recruitment files are made.

The report of the severe adverse events (SAE) should be submitted in time if any SAE or any other un-anticipated adverse event,which will affect the risk-reward ratio of this study occurs.

Researchers should submit the report of study progress before one month of the deadline according to the frequency of ethical review.

A summary report of the study progressshould be submitted to the IRB of the leading center. In any condition which will greatly affect the progress of the study or increase the potential risk of the subjects, a written report should be submitted by the applicant to IRB.

A protocol violation report should be submitted by the applicant/monitor/researcher in the following conditions: 1) conditions that violate the study protocol: subjects who did not meet the inclusion criteria, or should be excluded according to the exclusion criteria were wrongly includedin the study; subjects do not withdraw from the study when he/she meet the rules of withdrawal; incorrect treatment or dose was given; prohibited combined medicine was used; 2) conditions that violate GCP principle: subjects' rights and health are badly affected; the science of study was badly affected.

A final report should be submitted when the study is completely done or stopped prematurely.	
Period of validity of this ethical approval document	From 2014-01-17 to 2015-01-16
Frequency of ethical review	Every 24 months
Contact	**Name:** Hua Wang/Hong Zhao
	Phone: +86-0731-85369233
Signature of Chairman of the review boards and ethics committees	

编号：AF/SC-08/01.0

伦理审查批件

批件号	湖南中医药大学第一附属医院伦理委员会 HN-LL-KY-2014-003-01		
项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的比较研究-多中心随机对照非劣效性试验		
项目来源	“十二五”国家科技支撑计划 2012BAI24B01		
研究单位	中国中医科学院广安门医院、四川大学华西医院、湖南中医药大学第一附属医院、天津中医药大学第一附属医院等		
主要研究者	章薇		
审查类别	初始审查	审查方式	快速审查
审查日期	2014.1.16	审查地点	医院会议室
审查委员	郭志华、贺菊乔，赵艳玲，陈其华，黄孟君，张志国，张月娟，谭劲，钟　晓		
批准文件	临床研究方案（版本号:VERSION2.0-20140102） 知情同意书（版本号: VERSION2.0）		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。 完成临床研究，请申请人提交结题报告。	
年度/定期跟踪审查频率	24 个月
有效期	自批件下发之日起一年内有效
联系人与联系电话	王华　赵鸿　0731-85369233
主任委员签字	
伦理委员会	湖南中医药大学第一附属医院伦理委员会　（盖章）
日期	2014 年 1 月 17 日

Institutional Review Board Documentation of Hubei Province Hospital of Traditional Chinese Medicine

Ethics Review Approval

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	HBZY2014-C006-01		
Research Unit	Hubei Province Hospital of Traditional Chinese Medicine		
Major researcher	Zhongyu Zhou, Chief physician		
Review Attribute	Initial Review/Re-review	**Review Method**	Expedited Review/Meeting Review
Review Date	2014-02-26/2014-03-10	**Review Place**	Hospital's Meeting Room
Name of Review members	Yuanchao Tu, Jianzhong Liu, Yanhong Guo, Lanbo Fei, Yegang Cheng, Xiaoqin Wang, Wenxi Gao, Zhongming Zhou, Xiaoxue Hu, Yanhong Shi, Shengli Wu		
Approval Documents	1. Study protocol (Version 2.0_20140102/2014-01-02) 2. Consent (Version 2.1_20140226/2014-02-26)		
Reviewers' Comments:	According to the 'Ethical Review of Biomedical Research Related to Human' formulated by Ministry of Public Health, 'Specifications for the quality control of drugs used in clinical trials in China Academy of Chinese Medical Sciences' formulated by State food and drug administration, 'The Provisions for Medical Device Classification', 'Guidelines for ethical review of clinical trials related to drugs', 'Standard for clinical research on ethical review and management of TCM clinical research' formulated by State Administration of Traditional Chinese Medicine(under the Ministry of Public Health), 'Declaration of Helsinki', 'International Moral Guide for biomedical research' formulated by Council for International Organizations of Medical Sciences, all the reviewers approved the conduction of this study. Please follow the principle of GCP and protocol of this study approved by the review boards and ethics committees and protect the rights of participants during the process of this study. If the starting time of the study is later than validity date of the ethical document, the ethical approval will be invalid and researchers should resubmit an application for ethical approval. If the major researcher have been altered or any amendments in the protocol, informed consent and recruitment advertisement have been made, the researchers should resubmit an application for ethical approval. If there are any severe adverse events or adverse events affecting the benefit of the research, the researchers should submit the report of adverse events in 15 days and submit the report of adverse events which cause death in 7 days. Researchers should submit report of progress of the study before one month of the deadline according to frequency of ethical review. Researchers should submit summary reports about circumstances severely affecting the ongoing of the study and increasing the risk of participants in time to review boards and ethics committees.		

	If the following circumstances happen in the whole process of this study, applicants/researchers/ inspectors should submit a report about reasons causing the violation of study design: 1. Participants who met the inclusion criteria. 2. Participants who met the provisions of termination but weren't terminated. 3. Participants who were given incorrect therapy or wrong doses of medication. 4. Participants who had taken forbidden combined medication according to the design of the study. 5. Any conditions which violating the principle of GCP and affecting the participants' rights/health or the scientific nature of the study. Please submit a report in time when the study is finished or terminated in advance.	
Frequency of ethical review	Every 12 months	
Contact	**Name:** Xin Zhang, Xuejun Chen	
	Phone: +86-027-88920956	
Signature of Chairman of the review boards and ethics committees		

湖北省中医院伦理委员会

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

伦理审查批件

Ethics Review Approval

批件号	HBZY2014-C006-01		
项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验		
申办者	“十二五”国家科技支撑计划		
研究单位	中国中医科学院广安门医院 北京中医药大学东直门医院 四川大学华西医院 湖南中医药大学附属衡阳医院 湖南中医药大学第一附属医院 湖北省中医院 江苏省中医院 陕西省中医院 天津中医药大学第一附属医院 青岛海慈医疗集团		
主要研究者	周仲瑜 主任医师		
审查类别	初始审查、复审	审查方式	会议审查、快速审查
审查日期	2014-02-26、03-10	审查地点	湖北省中医院伦理办会议室
审查委员	涂远超、刘建忠、郭艳红、赞兰波、程业刚、王小琴、高文喜、周忠明、胡晓雪、石艳红、吴胜利		
批准文件	临床试验方案版本号/日期：VERSION 2.0_20140102/2014-01-02； 知情同意书版本号/日期：VERSION 2.1_20140226/2014-02-26		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》(2007)、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书开展该项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告。

出现没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交结题报告。

跟踪审查频率	12 个月
有效期	12 个月
联系人与联系电话	张馨、陈学军 027-88920956
主任委员签字	涂远超

湖北省中医院伦理委员会（盖章）

日期：2014 年 03 月 12 日

Institutional Review Board Documentation of Jiangsu Province Hospital of Traditional Chinese Medicine

Ethics Review Approval

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	2014NL-019-03	**Project Sponsor**	the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People's Republic of China
Research Unit	Jiangsu Province Hospital of Traditional Chinese Medicine		
Site PI	Jianhua Sun	**Research Department**	Department of Acupuncture
Review Attribute	Re-review	**Review Method**	Expedited review
Review Date	2014-04-11	**Review Place**	The meeting room of Guang'anmen Hospital
Name of Review members	Liping Yin		
Approval Documents	1. Study protocol (Version 2.0_2014-01-02) 2. Consent (Version 4.0) 3. Other materials		
Reviewers' Comments:	According to the 'Ethical Review of Biomedical Research Related to Human' formulated by Ministry of Public Health, 'Specifications for the quality control of drugs used in clinical trials in China Academy of Chinese Medical Sciences' formulated by State food and drug administration, 'The Provisions for Medical Device Classification', 'Guidelines for ethical review of clinical trials related to drugs', 'Standard for clinical research on ethical review and management of TCM clinical research' formulated by State Administration of Traditional Chinese Medicine(under the Ministry of Public Health), 'Declaration of Helsinki', 'International Moral Guide for biomedical research' formulated by Council for International Organizations of Medical Sciences, all the reviewers approved the conduction of this study. Please follow the principle of GCP and protocol of this study approved by the review boards and ethics committees and protect the rights of participants during the process of this study. If the starting time of the study is later than validity date of the ethical document, the ethical approval will be invalid and researchers should resubmit an application for ethical approval. If the major researcher have been altered or any amendments in the protocol, informed consent and recruitment advertisement have been made, the researchers should resubmit an application for ethical approval. If there are any severe adverse events or adverse events affecting the benefit of the research, the researchers should submit the report of adverse events in 15 days and submit the report of adverse events which cause death in 7 days. Researchers should submit report of progress of the study before one month of the deadline according to frequency of ethical review. Researchers should submit summary reports about circumstances severely		

	affecting the ongoing of the study and increasing the risk of participants in time to review boards and ethics committees. If the following circumstances happen in the whole process of this study, applicants/researchers/ inspectors should submit a report about reasons causing the violation of study design: 1. Participants who met the inclusion criteria. 2. Participants who met the provisions of termination but weren't terminated. 3. Participants who were given incorrect therapy or wrong doses of medication. 4. Participants who had taken forbidden combined medication according to the design of the study. 5. Any conditions which violating the principle of GCP and affecting the participants' rights/health or the scientific nature of the study. Please submit a report in time when the study is finished or terminated in advance.
Period of validity of this ethical approval document	From 2014-04-11 to 2015-04-11
Frequency of ethical review	Every 12 months
Contact	Jing Wu, Tel. +86-025-86560515
Signature of Chairman of the review boards and ethics committees	

伦理审查批件

批件号	2014NL-019-03		
项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验		
项目来源	“十二五”国家科技支撑计划		
研究单位	江苏省中医院，中国中医科学院广安门医院		
主要研究者	孙建华		
审查类别	复审申请	审查方式	快速审查
审查日期	2014 年 04 月 11 日	审查地点	
审查委员	殷立平		
审查批准文件	临床研究方案 版本号：VERSION 2.0 版本日期：2014-01-02 招募受试者的材料 修改的知情同意书 版本号：VERSION 4.0		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》(2007)、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究开始前，请申请人完成临床试验注册。研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。发生严重不良事件，请申请人及时提交严重不良事件报告；紧急报告之后，尽快提交详细的严重不良事件随访报告。请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。完成临床研究，请申请人提交结题报告。本项临床试验应当在批准之日起一年内实施，逾期未实施的，本批件自行废止。

年度/定期跟踪审查频率	请于 2015 年 04 月 11 日前 1 个月提交研究进展报告
有效期	12 个月
联系人与联系电话	吴静　025-86560515
主席签字	
伦理委员会	南京中医药大学附属医院（江苏省中医院）伦理委员会（盖章）
日期	2014 年 04 月 11 日

Institutional Review Board Documentation of Shaanxi Province of Traditional Chinese Medicine

Ethics Review Approval

<table>
<tr><td>Project Title</td><td colspan="5">Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women</td></tr>
<tr><td>Applicant Site</td><td colspan="5">Acupuncture and Moxibustion Department, Shaanxi Province Hospital of TCM</td></tr>
<tr><td>Sponsor</td><td colspan="5">the 12th Five-year Plan of the National Key Technology Support Program by the Ministry of Science and Technology of the People’s Republic of China (2012BAI24B01)</td></tr>
<tr><td>Department</td><td>Acupuncture and Moxibustion</td><td>Site PI</td><td>Tongsheng Su</td><td>Title</td><td>Chief Physician</td></tr>
<tr><td>Meeting Date</td><td>2014-03-14</td><td>Meeting Place</td><td>Conference Room</td><td>Review Type</td><td>Meeting Review</td></tr>
<tr><td>Review Files</td><td colspan="5">1. study protocol (VERSION 2.0_20140102);
2. Case Report Form (VERSION2.0_20140102);
3. Informed Consent (VERSION2.0);
4. Researchers’ CV, Personnel Allocation, Equipment and Facility;</td></tr>
<tr><td>Review Contents</td><td colspan="5">Researchers’ Qualification:
Meet Requirement ■ Not Meet Requirement □
Personnel Allocation:
Meet Requirement ■ Not Meet Requirement □
Equipment and Facility:
Meet Requirement ■ Not Meet Requirement □
Informed Consent:
Meet Requirement ■ Not Meet Requirement □
Informed Consent Obtained:
Appropriate ■ Not Appropriate □
Study Protocol Meet:
Requirement ■ Not Meet Requirement □
Subjects’ AE or Accident:
With Effective Emergency Measures ■
Without Effective Emergency Measures □
With Compensation ■
Without Compensation □</td></tr>
<tr><td rowspan="2">Review Comments</td><td>Approved</td><td>Approved after revision</td><td>Review after revision</td><td>Not approved</td><td>Terminated/paused</td></tr>
<tr><td>7</td><td>1</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Attendance People</td><td>Anticipated: 9</td><td>Participated: 9</td><td colspan="2">Avoided: 1</td><td>Left: 0</td></tr>
<tr><td colspan="6">Approval Comments: The study protocol of this trial conforms to the requirements, but the informed consent needs to be revised. Subjects should be informed that the control group uses plocebo treatment. The study will be approved after revision.</td></tr>
<tr><td>Director signature:
Guangyang Wei
Date: 2014-03-14</td><td colspan="3">Meeting Recorder:
Yifei Zhao
Date: 2014-03-14</td><td colspan="2">Telephone: +86-029-87251691</td></tr>
</table>

陕西省中医医院伦理委员会

临床研究伦理审查批件

（2014）伦审第（02）号

项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较-多中心随机对照非劣效性试验				
申请单位	陕西省中医医院针灸科				
项目来源	国家科技支撑计划	项目编号：2012BAI24B00	课题编号：2012BAI24B01		
承担研究任务科室	针灸科	主要研究者	苏同生	职称	主任医师
会议时间	2014 年 03 月 14 日	会议地点	行政四楼小会议室	审查方式	会议审查
审查文件	1、临床研究方案（版本号及日期：VERSION2.0_20140102）； 2、病例报告表（版本号及日期：VERSION2.0_20140102）； 3、知情同意书（版本号及日期：VERSION2.0）； 4、研究者专业履历及专业科室人员配备、设备设施情况；				
审查内容	研究者的资格： 人员配备： 设备条件： 知情同意书： 获取知情同意书的方法： 研究方案： 受试者因参加临床试验发生不良反应或意外：	符合要求■ 符合要求■ 符合要求■ 符合要求■ 恰当■ 符合要求■ 有有效抢救措施■ 有补偿规定■	不符合要求□ 不符合要求□ 不符合要求□ 不符合要求□ 不恰当□ 不符合要求□ 无有效抢救措施□ 无补偿规定□		

审查意见	同意	作必要的修改后同意	作必要的修正后重审	不同意	终止或暂停已批准的研究
	7 人	1	0	0	0

出席人数	应到：9 人	实到：9 人	回避：1 人(投票时)	请假：0 人
审批意见：经审查该项目符合 GCP、《赫尔辛基宣言》要求，同意开展临床研究。				
主任委员签字： 日期：2014 年 3 月 14 日		会议记录者签字： 日期：2014 年 3 月 14 日		联系电话：029-87251691

Institutional Review Board Documentation of Qingdao Haici Medical Center

Ethics Review Approval

Title of the study	Effect of electroacupuncture versus pelvic floor muscle training plus solifenacin for moderate and severe mixed urinary incontinence in women		
Ethics approval number	2014-1-1	Project Sponsor	The National Key Technology Support Program
Research Unit	Qingdao Haici Medical Center		
Major researcher	Lian Liu	**Department of the researchers**	Department of Acupuncture
Review Type	Initial Review	**Review Method**	expedited review
Review Date	2014-02-27	**Review Place**	Qingdao Haici Medical Center
Name of Review members	Shunchang Sun, Baotong Wu, Jieping Li		
Approval Documents	Study protocol (Version 2.0_20140102), Consent (Version 2.0), Case Report Form (Version 2.0_20140102), Recruitment advertisement (Version 2.0_20140102), Researcher Handbook (Version 2.0_20140102), bladder diary (Version 1.0_20131218)		
Reviewers' Comments:	According to the 'Ethical Review of Biomedical Research Related to Human' formulated by Ministry of Public Health, 'Specifications for the quality control of drugs used in clinical trials in China Academy of Chinese Medical Sciences' formulated by State food and drug administration, 'The Provisions for Medical Device Classification', 'Guidelines for ethical review of clinical trials related to drugs', 'Standard for clinical research on ethical review and management of TCM clinical research' formulated by State Administration of Traditional Chinese Medicine(under the Ministry of Public Health), 'Declaration of Helsinki', 'International Moral Guide for biomedical research' formulated by Council for International Organizations of Medical Sciences, all the reviewers approved the conduction of this study. Please follow the principle of GCP and protocol of this study approved by the review boards and ethics committees and protect the rights of participants during the process of this study. If the starting time of the study is later than validity date of the ethical document, the ethical approval will be invalid and researchers should resubmit an application for ethical approval. If the major researcher have been altered or any amendments in the protocol, informed consent and recruitment advertisement have been made, the researchers should resubmit an application for ethical approval. If there are any severe adverse events or adverse events affecting the benefit of the research, the researchers should submit the report of adverse events in 15 days and submit the report of adverse events which cause death in 7 days. Researchers should submit report of progress of the study before one month of the deadline according to frequency of ethical review. Researchers should submit summary reports about circumstances severely affecting the ongoing of the study and increasing the risk of participants in time to review boards and ethics committees. If the following circumstances happen in the whole process of this study, applicants/researchers/ inspectors should submit a report about reasons causing the violation of study design: 1. Participants who met the inclusion criteria. 2. Participants who met the provisions of termination but weren't terminated. 3. Participants who were given incorrect therapy or wrong doses of medication. 4. Participants who had taken		

	forbidden combined medication according to the design of the study. 5. Any conditions which violating the principle of GCP and affecting the participants' rights/health or the scientific nature of the study. Please submit a report in time when the study is finished or terminated in advance.
Period of validity of this ethical approval document	From 2014-01-18 to 2015-01-17
Contact	**Name:** Hong Liu
Signature of Chairman of the review boards and ethics committees	

档号 2014-1
序号 1 页数 2

伦理审查批件

项目名称	电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较：多中心随机对照非劣效性试验		
批件号	2014-1-1	项目来源	国家级课题
研究单位	中国中医科学院广安门医院，北京中医药大学东直门医院，四川大学华西医院，天津中医药大学第一附属医院，湖南中医药大学附属衡阳医院，湖南中医药大学第一附属医院，湖北省中医院，江苏省中医院，陕西省中医院，青岛市海慈医疗集团		
申办者	无		
主要研究者	刘立安	研究科室	针灸科
审查类别	初审	审查方式	快速审查
审查日期	2014 年 2 月 27 日	审查地点	青岛市海慈医疗集团
审查委员	孙顺昌、武宝通、李界平		
批准文件及版本	研究方案（VERSION 2.0_20140102），知情同意书（VERSION 2.0），病例报告表（VERSION 2.0_20140102），招募广告（VERSION 2.0_20140102），研究者手册（VERSION 2.0_20140102），排尿日记卡（VERSION 1.0_20131218）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》、国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康和权利。 若在本批件有效期内未启动研究，本批件作废，需重新提交伦理审查申请。 研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。		

Sun B, *et al*. *BMJ Support Palliat Care* 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

有效期	2014 年 1 月 18 日～2015 年 1 月 17 日
联系人与联系电话	
主任委员签字	刘宏
	青岛市海慈医疗集团伦理委员会（盖章）
	日期： 2014 年 2 月 27 日

第 2 页/共 2 页

Sun B, *et al*. *BMJ Support Palliat Care* 2020;0:1–7. doi: 10.1136/bmjspcare-2019-002034

Appendix 2

2.1 Assessment time and measures of the two trials.[a]

	72h IEF		1h AUL		ICIQ-SF score	
Week	**MUI trial**	**SUI trial**	**MUI trial**	**SUI trial**	**MUI trial**	**SUI trial**
0	√	√	√	√	√	√
2	√			√		
4	√	√	√		√	
6	√	√		√		√
8	√				√	
10	√					
12	√		√		√	
15		√				
16	√	√			√	
17		√				
18		√				√
20	√				√	
24	√				√	
27		√				
28	√	√			√	
29		√				
30		√				√
32	√				√	
36	√				√	

Abbreviations: SUI, Stress urinary incontinence; MUI, mixed urinary incontinence; IEF, incontinence episode frequency; AUL, the amount of urine; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

a.√ means that the measures of the original trials were conducted at the corresponding time point, and the blank space indicates that no measures were conducted.

2.2 The data of changes in the mean 72-h, 1h AUL and ICIQ-SF score of Fig. 1.

Time	**Elderly (N=92)**	**Non-elderly (N=292)**	**Difference (95% CI)**	***p*-value**
Changes in the mean 72-h IEF, mean (95% CI)				
Week 2	-2.0(-3.0 to -1.0)	-1.8(-2.4 to -1.3)	0.2(-1.0 to 1.4)	0.773
Week 4	-3.0(-4.1 to -1.9)	-2.8(-3.3 to -2.2)	0.2(-1.1 to 1.5)	0.733
Week 6	-4.1(-5.2 to -3.1)	-3.9(-4.4 to -3.3)	0.3(-1.0 to 1.5)	0.688

Week 8	-3.3(-4.7 to -1.9)	-4.9(-5.7 to -4.1)	-1.6(-3.3 to 0.1)	0.066
Week10	-4.1(-5.4 to -2.7)	-5.6(-6.4 to -4.9)	-1.6(-3.2 to 0.1)	0.059
Week 12	-4.1(-5.4 to -2.8)	-6.6(-7.3 to -5.8)	-2.5(-4.1 to -0.9)	0.003
Week 15	-6.0(-7.0 to -5.0)	-4.3(-4.8 to -3.8)	1.7(0.5 to 2.9)	0.007
Week 16	-5.5(-6.3 to -4.6)	-5.3(-5.7 to -4.8)	0.2(-0.8 to 1.2)	0.722
Week 17	-6.3(-7.3 to -5.3)	-4.5(-5.0 to -4.0)	1.8(0.6 to 3.0)	0.003
Week 18	-5.9(-7.0 to -4.8)	-4.6(-5.2 to -4.1)	1.2(-0.002 to 2.5)	0.050
Week 20	-5.4(-6.9 to -4.0)	-7.1(-8.0 to -6.3)	-1.7(-3.5 to 0.1)	0.061
Week 24	-5.7(-7.1 to -4.2)	-7.3(-8.2 to -6.5)	-1.7(-3.4 to 0.1)	0.061
Week 27	-6.0(-7.1 to -4.8)	-4.6(-5.2 to -4.0)	1.4(0.1 to 2.8)	0.040
Week 28	-6.2(-7.1 to -5.3)	-5.7(-6.2 to -5.2)	0.5(-0.5 to 1.5)	0.343
Week 29	-6.3(-7.4 to -5.2)	-4.8(-5.4 to -4.3)	1.4(0.2 to 2.7)	0.026
Week 30	-6.4(-7.5 to -5.2)	-5.1(-5.6 to -4.5)	1.3(-0.04 to 2.6)	0.057
Week 32	-6.8(-8.2 to -5.3)	-7.9(-8.5 to -6.9)	-0.9(-2.7 to 0.8)	0.294
Week 36	-7.3(-8.6 to -6.0)	-8.2(-9.0 to -7.5)	-0.9(-2.5 to 0.7)	0.260
Changes in the mean1h AUL(g), mean (95% CI)				
Week 2	-3.4(-7.0 to 0.1)	-6.1(-8.0 to -4.3)	-2.7(-6.8 to 1.5)	0.209
Week 4	-7.5(-10.5 to -4.5)	-7.1(-8.9 to -5.3)	0.4(-3.2 to 4.1)	0.808
Week 6	-8.4(-11.7 to -5.1)	-10.0(-11.6 to -8.3)	-1.5(-5.4 to 2.3)	0.441
Week 12	-11.1(-14.2 to -7.9)	-12.4(-14.2 to -10.5)	-1.3(-5.2 to 2.5)	0.496
Changes in the meanICIQ-SF score, mean (95% CI)				

Week 4	-2.0(-2.7 to -1.2)	-2.5(-3.0 to -2.0)	-0.6(-1.5 to 0.4)	0.256
Week 6	-2.5(-3.2 to -1.8)	-2.4(-2.8 to -2.1)	0.1(-0.7 to 0.9)	0.869
Week 8	-3.9(-4.8 to -2.9)	-4.4(-5.0 to -3.8)	-0.5(-1.7 to 0.7)	0.403
Week 12	-4.8(-6.0 to -3.6)	-6.3(-7.0 to -5.6)	-1.5(-2.9 to 0.02)	0.054
Week 16	-5.5(-6.7 to -4.3)	-6.9(-7.7 to -6.2)	-1.4(-2.9 to 0.1)	0.061
Week 18	-4.3(-5.2 to -3.3)	-3.5(-3.9 to -3.0)	0.8(-0.3 to 1.9)	0.151
Week 20	-6.1(-7.4 to -4.9)	-7.1(-7.9 to -6.4)	-1.0(-2.5 to 0.5)	0.201
Week 24	-6.7(-8.0 to -5.5)	-7.3(-8.0 to -6.6)	-0.6(-2.1 to 0.9)	0.457
Week 28	-7.0(-8.2 to -5.7)	-7.4(-8.1 to -6.6)	-0.4(-1.9 to 1.1)	0.598
Week 30	-4.7(-5.7 to -3.8)	-3.9(-4.4 to -3.5)	0.8(-0.3 to 1.9)	0.152
Week 32	-7.1(-8.3 to -5.9)	-7.4(-8.1 to -6.7)	-0.3(-1.7 to 1.2)	0.710
Week 36	-7.7(-8.9 to -6.5)	-7.5(-8.2 to -6.9)	0.1(-1.3 to 1.6)	0.860

Abbreviations: IEF, incontinence episode frequency; AUL, the amount of urine; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form.

All results presented in the table and in the manuscript are based on consistent use of data for completers, without imputation.