

APPENDIX 9: RANDOMIZED CONTROLLED TRIALS OF KERATINOCYTE GROWTH FACTOR FOR THE PREVENTION OF ORAL MUCOSITIS IN ADULT AND PEDIATRIC PATIENTS RECEIVING TREATMENT FOR CANCER OR UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION – METHODOLOGY

METHODOLOGY					RISK OF BIAS FOR RANDOMIZED CONTROL TRIALS					
First Author (Year)	RCT or quasi-RCT	Study Design: (Parallel group, Cross-over, N-of-1)	Scales Used to Measure Mucositis	Frequency and Timing of Mucositis Assessment	Adequate sequence generation?	Adequate allocation concealment?	Participants and personnel blinded?	Outcome assessors blinded?	Loss to follow-up is less than 20% and/or equally distributed between both interventions?	Study free of selective reporting?
Blijlevens (2013) [1]	RCT	Parallel	WHO	Daily from day 2 to day 32	Yes	Unclear	Yes	Yes	Yes	Yes
Jagasia (2012) [2]	RCT	Parallel	WHO	First day of the conditioning regimen until discharge or day 28	Unclear	Unclear	Yes	Yes	Yes	Yes
Le (2011) [3]	RCT	Parallel	WHO	Twice weekly during chemo-radiotherapy for 15 weeks	Unclear	Yes	Yes	Yes	Yes	Yes
Henke (2011) [4]	RCT	Parallel	WHO	Twice-weekly during radio-chemotherapy for 15 weeks	Yes	Yes	Yes	Yes	Yes	Yes
Vadhan_Raj (2010) [5]	RCT	Parallel	WHO, CTCAE	Before chemotherapy and days 10, 12 and 14	Yes	Yes	Yes	Yes	Yes	Yes
Brizel (2008) [6]	RCT	Parallel	CTCAE v2.0 and RTOG	Once weekly for 12 weeks, weeks 14, 16, 18 and 20	Unclear	Unclear	Yes	Yes	Yes	Yes
Rosen (2006) [7]	RCT	Parallel	WHO, OMDQ	Baseline, days 1, 4, 8, 12, 15, and at the end of both cycles 1 and 2	Unclear	Unclear	Yes	Yes	Yes	Yes
Blazar (2006) [8]	RCT	Parallel	WHO	3 times per week during hospitalization	Unclear	Unclear	Yes	Yes	Yes	Yes
Freytes (2004) [9]	RCT	Parallel	CTCAE, OMAS	Day 0 and three times per week until mucositis resolved	Unclear	Unclear	Yes	Yes	Yes	Yes
Spielberger (2004) [10] (companion paper: [11])	RCT	Parallel	WHO, RTOG, Western Consortium Cancer Nursing Research Scale	Daily for 28 days after HSCT	Unclear	Unclear	Yes	Yes	Yes	Yes
Meropol (2003) [12]	RCT	Parallel	WHO	Days 1, 4, 8, 15, and 28 after chemotherapy	Unclear	Unclear	Yes	Yes	Yes	Yes

Abbreviations: RCT – randomized controlled trial; WHO – World Health Organization; CTCAE – Common Terminology Criteria for Adverse Events; RTOG – Radiation Therapy Oncology Group; OMDQ – Oral Mucositis Daily Questionnaire; HSCT – hematopoietic stem cell transplantation

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