

APPENDIX 12: RANDOMIZED CONTROLLED TRIALS OF ANY INTERVENTION FOR THE PREVENTION OF ORAL MUCOSITIS IN 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?
Patte (2002) [1]	RCT	Parallel	Unclear	Unclear	Unclear	Unclear	No	No	Yes	Yes
Michel (2000) [2]	RCT	Parallel	Not reported	Unclear	Unclear	Unclear	No	No	Yes	Yes
Lehrnbecher (2007) [3]	RCT	Parallel	CTCAE v3.0	Unclear	Unclear	Yes	No	No	Yes	Yes
Ladenstein (2010) [4]	RCT	Parallel	CTCAE v2.0	Unclear	Yes	Yes	No	No	Yes	Yes
Cesaro (2013) [5]	RCT	Parallel	WHO	Unclear	Yes	Yes	No	No	Yes	Yes
Fox (2009) [6]	RCT	Parallel	CTCAE v2.0	Unclear	Unclear	Yes	No	No	Yes	Yes
Wexler (1996) [7]	RCT	Parallel	CTCAE	Unclear	Unclear	Unclear	No	No	Yes	Yes
Uderzo (2011) [8]	RCT	Parallel	WHO	Unclear	Yes	Yes	Yes	Yes	Yes	No
Aquino (2005) [9]	RCT	Parallel	Modified Walsh scale	Daily until day 28 post HSCT or discharge	Yes	Yes	Yes	Yes	Yes	Yes
Ward (2009) [10]	Quasi-RCT	Cross-over	CTCAE v2.0	Days 1 to 21, frequency unclear	No	No	No	No	No	Yes
Sencer (2012) [11]	RCT	Parallel	Modified Walsh scale, WHO	Daily from day -1 to day 20 post HSCT	Unclear	Unclear	Yes	Yes	Yes	Yes
Oberbaum (2001) [12] (companion paper: [13])	RCT	Parallel	WHO	Every 2 days until no symptoms for 2 days, 14 days minimum after the start of study agent	Unclear	Yes	Yes	Yes	Yes	Yes
Abramoff (2008) [14]	RCT	Parallel	CTCAE v2.0	Before and after each laser application	Unclear	Unclear	Yes	Yes	Yes	No
Cruz (2007) [15]	RCT	Parallel	CTCAE v2.0	Days 1, 8 and 15	Unclear	Unclear	No	Yes	Yes	Yes
Raether (1989) [16]	RCT	Parallel	Percentage of ulcerated mucosa	Twice weekly from 8 days prior to HSCT until day 35 or discharge	Unclear	Unclear	Yes	Yes	Yes	Yes
Cheng (2004) [17] (companion papers: [18], [19])	RCT	Cross-over	Modified Oral Assessment Guide, WHO, VAS	Twice weekly	Unclear	Unclear	No	No	Yes	Yes
Shenep (1988) [20]	RCT	Parallel	Study-specific ulceration scale	Twice weekly	Yes	Yes	Yes	Yes	Yes	Yes

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?
Sung (2007) [21]	RCT	N-of-1	OMAS, VAS, WHO	Days 7, 10, 14, and 17 of each study cycle.	Yes	Yes	Yes	Yes	Yes	Yes
de Koning (2007) [22]	RCT	Cross-over	WHO	2 days before start of chemotherapy cycle daily until full recovery of patient's condition.	Unclear	Yes	No (personnel not blinded)	Yes	Yes	Yes
Gandemer (2007) [23]	RCT	Parallel	WHO	Daily for 3 weeks starting at beginning of chemotherapy	Yes	Yes	No	No	Yes	Yes
Rojas de Morales (2001) [24]	RCT	Parallel	Rutkauskas Index	Twice a week when in hospital	Unclear	Unclear	No	No	No	No

Abbreviations: RCT – randomized controlled trial; WHO – World Health Organization; CTCAE – Common Terminology Criteria for Adverse Events; VAS – visual analogue scale; HSCT – hematopoietic stem cell transplantation

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