

**APPENDIX 4: RANDOMIZED CONTROLLED TRIALS OF CRYOTHERAPY FOR THE PREVENTION OF ORAL MUCOSITIS IN ADULT AND PEDIATRIC PATIENTS RECEIVING TREATMENT FOR CANCER OR UNDERGOING HEMATOPOIETIC STEM CELL TRANSPLANTATION – STUDY CHARACTERISTICS**

STUDY CHARACTERISTICS AND PARTICIPANTS												
First Author (Year)	Enrollment Year		Country of Patient Enrollment	Pharma Sponsorship Declared	Total N Randomized	Age (Pediatric, Adult, Both)	Specific Cancer Diagnoses	Population Type (Cancer, HSCT, Both)	Transplant Type	Treatment Related to Cryotherapy	Duration of Cryotherapy	Radiotherapy in Oral Area
	Start	End										
Katranci (2012) [1]	NR	NR	Turkey	No	60	Adult	Various	Cancer	NA	5-FU, leukovorin	30 minutes	No
Salvador (2012) [2]	2007	2007	Canada	No	46	Adult	Multiple myeloma	HSCT	Auto	Melphalan	60 minutes	No
Sorensen (2008)[3]	2001	2005	Denmark	No	225	Adult	Gastro-intestinal cancer	Cancer	NA	5-FU, leukovorin	45 minutes	No
Svanberg (2007) [4] (companion papers: [5], [6])	2002	2004	Sweden	No	78	Adult	Various	HSCT	Auto, allo	Various	Throughout chemotherapy session	Sometimes
Gori (2007) [7]	2004	2006	Italy	No	130	Both	Hem diagnosis	HSCT	Allo	Methotrexate	At least 1 hour	Sometimes
Papadeas (2007) [8]	NR	NR	Greece	No	85	Adult	Unclear	Cancer	NA	5-FU, leukovorin	50 minutes	No
Lilleby (2006) [9]	2003	2005	US	No	41	Adult	Multiple myeloma	HSCT	Auto	Melphalan	7 hours	No
Baydar (2005) [10]	NR	NR	Turkey	No	99	Adult	Various	Cancer	NA	5-FU, leukovorin	From start of 5-FU until 10 minutes after	No
Karagozoglu (2005) [11]	2000	2001	Turkey	No	60	Adult	Various	Cancer	NA	Etoposide, cisplatin, mitomycin-C, vinblastine	Throughout chemotherapy infusion	No
Nikoletti (2005) [12]	NR	NR	Australia	No	79	Adult	Various	Cancer	NA	5-FU, leukovorin	30 minutes	No
Cascinu (1994) [13]	NR	NR	Italy	NR	84	Adult	Various	Cancer	NA	5-FU, leukovorin	30 minutes	No
Rocke (1993) [14]	NR	NR	US	No	179	Adult	Unclear	Cancer	NA	5-FU, leukovorin	60 minutes	No
Mahood (1991) [15]	NR	NR	US	No	95	NR	Unclear	Cancer	NA	5-FU, leukovorin	30 minutes	No
Kakoei (2013) [16]	NR	NR	Iran	No	40	Adult	Head and neck cancer	Cancer	NA	Radiotherapy	10 minutes	Yes

Abbreviations: NR - not reported; NA - not applicable; pharma – pharmaceutical company; N – number; hem – hematological; HSCT - hematopoietic stem cell transplantation; auto – autologous; allo – allogeneic; 5-FU – 5-fluorouracil; US – United States

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