APPENDIX 11: 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 – STUDY CHARACTERISTICS

STUDY CHARACTERISTICS AND PARTICIPANTS

First Author (Year)	Enrollment Year		Country of Patient Enrollment	Pharma Sponsorship Declared	Total N Randomized	Age Range	Specific Cancer Diagnosis	Population Type (Cancer, HSCT, Both)	Transplant Type	Treatment (Chemo alone, Radiation alone, Both, Not specified)	Treatment Regimen in Related to Intervention
	Start	End									
Patte (2002) [1]	1994	1996	France	No	149	NR	NHL	Cancer	NA	Chemo	COPADM
Michel (2000) [2]	1993	1998	France	No	67	NR	High risk ALL	Cancer	NA	Chemo	R3 and COPADM for 6 cycles total
Lehrnbecher (2007) [3]	1998	2003	Germany	No	317	0 to 18	AML	Cancer	NA	Chemo	Induction AML
Ladenstein (2010) [4]	2002	2005	16 European countries	Yes	239	1 to 17	High risk neuroblastoma	Cancer	NA	Chemo	Rapid COJEC
Cesaro (2013) [5]	2007	2011	Italy	No	61	1.1 to 16.8	Various	HSCT	Auto	Both	Various
Fox (2009) [6]	2000	2005	US	Yes	34	3.8 to 25.8	Sarcoma	Cancer	NA	Both	VDC and IE
Wexler (1996) [7]	NR	NR	US	No	37	1 to 24	Sarcoma	Cancer	NA	Both	NCI protocol 86C 169
Uderzo (2011) [8]	2005	2008	Italy	No	120	0.4 to 18.6	Hem malignancy	HSCT	Allo	Both	Timing based on HSCT, not conditioning
Aquino (2005) [9]	1998	2002	US	No	130	NR	Various	HSCT	Auto, allo	Both	Various
Ward (2009) [10]	1999	2005	UK	Yes	76	1 to 22	Various	Cancer	NA	Chemo	Various
Sencer (2012) [11]	2004	2006	US, Israel	No	195	3 to 25	Various	HSCT	Auto, allo	Not specified	Timing based on HSCT, not conditioning
Oberbaum (2001) [12] (companion paper: [13])	NR	NR	Israel	No	32	3 to 25	Various	HSCT	Auto, allo	Not specified	Various
Abramoff (2008) [14]	2003	2003	Brazil	Yes	22	7 to 23	Osteosarcoma and ALL	Cancer	NA	Chemo	Various
Cruz (2007) [15]	2003	2005	Brazil	Yes	62	3 to 18	Various	Both	Unclear	Chemo	Various
Raether (1989) [16]	1986	1987	US	Yes	47	1.6 to 21.5	Various	HSCT	Auto, allo	Both	Various
Cheng (2004) [17] (companion papers:[18] [19])	2000	2001	Hong Kong	No	40	6 to 16	Various	Cancer	NA	Chemo	Various
Shenep (1988) [20]	1983	1987	US	Yes	48	NR	AML	Cancer	NA	Chemo	Induction AML
Sung (2007) [21]	2001	2004	Canada	Yes	45	6.4 to 15.1	Various	Cancer	NA	Chemo	Doxorubicin

STUDY CHARACTERISTICS AND PARTICIPANTS											
First Author (Year)	Enrollment Year		Country of Patient Enrollment	Pharma Sponsorship Declared	Total N Randomized	Age Range	Specific Cancer Diagnosis	Population Type (Cancer, HSCT, Both)	Transplant Type	Treatment (Chemo alone, Radiation alone, Both, Not specified)	Treatment Regimen in Related to Intervention
	Start	End									
de Koning (2007) [22]	2001	2004	Netherlands	Yes	30	1 to 14	Various	Cancer	NA	Chemo	Various
Gandemer (2007) [23]	1999	2002	France	Yes	145	5.2 to 18.7	Various	Both	Auto, allo	Chemo	Various
Rojas de Morales (2001) [24]	1998	1999	Venezuela	Yes	16	5 to 12	ALL or lymphoma	Cancer	NA	Chemo	Not stated

Abbreviations: NR - not reported; NA - not applicable; pharma – pharmaceutical company; N – number; HSCT - hematopoietic stem cell transplantation; chemo – chemotherapy; NHL – non-Hodgkin's lymphoma; ALL - acute lymphoblastic leukemia; AML – acute myeloid leukemia; auto – autologous; allo – allogeneic; hem – hematological; COPADM - cyclophosphamide, vincristine, prednisone, doxorubicin and methotrexate; R3 - high-dose cytarabine, etoposide and dexamethasone; COJEC - cisplatin, vincristine, carboplatin, etoposide and cyclophosphamide; VDC - vincristine, doxorubicin and cyclophosphamide; IE – ifosphamide and etoposide; NCI – National Cancer Institute; US – United States; UK – United Kingdom

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