

**APPENDIX 8: 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 – STUDY CHARACTERISTICS**

<b>STUDY CHARACTERISTICS AND PARTICIPANTS</b>											
First Author (Year)	Enrollment Year		Country of Patient Enrollment	Pharma Sponsorship Declared	Total N Randomized	Age (Pediatric, Adult, Both)	Specific Cancer Diagnosis	Population Type (Cancer, HSCT, Both)	Transplant Type	Treatment (Chemo alone, Radiation alone, Both, Not specified)	Treatment Related to KGF
	Start	End									
Blijlevens (2013) [1]	2006	2009	Europe	Yes	281	Adult	Multiple myeloma	HSCT	Auto	Chemo alone	Melphalan
Jagasia (2012) [2]	2005	2008	US and Australia	Yes	155	Adult	Hem malignancy	HSCT	Allo	Both	Variable
Le (2011) [3]	2005	2007	North America and Europe	Yes	188	Adult	Advanced head and neck cancer	Cancer	NA	Both	Cisplatin, radiotherapy (no surgery)
Henke (2011) [4]	2005	2007	Australia, Canada, Europe	Yes	186	Adult	Advanced head and neck cancer	Cancer	NA	Both	Cisplatin, radiotherapy (post-operative)
Vadhan-Raj (2010) [5]	2005	2008	US	Yes	48	Both	Sarcoma	Cancer	NA	Chemo alone	Doxorubicin
Brizel (2008) [6]	1999	2001	Australia, Canada, US	Yes	100	Adult	Advanced head and neck squamous cell carcinoma	Cancer	NA	Both	Cisplatin, 5-FU, radiotherapy
Rosen (2006) [7]	NR	NR	NR	Yes	65	Adult	Metastatic colon cancer	Cancer	NA	Chemo alone	5-FU, leukovorin
Blazar (2006) [8]	NR	NR	US	Yes	100	Both	Hem malignancy	HSCT	Allo	Both	Cyclophosphamide with TBI or busulphan
Freytes (2004) [9]	NR	NR	US	Yes	52	Adult	Hem malignancy	HSCT	Auto	Both	Variable
Spielberger (2004) [10](companion paper: [11])	2001	2002	US	Yes	214	Adult	Hem malignancy	HSCT	Allo	Both	Etoposide, cyclophosphamide, TBI
Meropol (2003) [12]	NR	NR	US	Yes	81	Adult	Metastatic colon or rectal cancer	Cancer	NA	Chemo alone	5-FU, leukovorin

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

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