

SPECTRA OPTIA® APHERESIS SYSTEM
MULTIPLE MYELOMA PATIENT STUDY

Study Description

- A multi-site U.S. clinical trial was conducted to evaluate Spectra Optia system’s mononuclear cell (MNC) collection protocol in patients with multiple myeloma
- 26 subjects from four investigational sites participated in the single-arm study
- 19 males and 7 females participated, ranging in age from 39 to 74 years (median of 62 years) and none had undergone a previous stem-cell transplant
- Subjects were mobilized, myeloablated and transplanted with the Spectra Optia-collected cells, according to each investigational site’s standard practice of care
- The primary outcome measure was days until neutrophil recovery, following myeloablation and stem cell reinfusion
- Secondary outcome measures characterized the system’s performance with respect to CD34+ collection efficiency, MNC collection efficiency, platelet collection efficiency and product purity
- No serious or unanticipated device-related events occurred during the investigation
- Reported adverse events were limited to the expected side effects of G-CSF mobilization, events associated with the subject’s primary illness and well-known sequelae associated with apheresis

Table 1: Data Summary

		Median	Minimum	Maximum	N
Pre Count	TBV (mL)	5,340	3,174	6,774	26
	WBC x 10 ³ /μL	30	3	71	26
	CD34+ /μL	63	5	772	26
	Platelets x 10 ³ /μL	122	38	332	26
	Weight of patient (kg)	89	56	123	26
Collected Product	CD34+ x 10 ⁶ /kg body weight	7.3	0.7	34.1	26
	Platelets x 10 ³ /μL	1,054	252	2,043	26
	Hct (%)	1.8	1.1	4.5	25
	Granulocyte (%)	29.0	4.0	72.0	25
	Volume (mL)	349	227	550	26
Procedure	CD34+ CE1 (%)	70	39	92	24
	CD34+ CE2 (%)	56	30	84	26
	MNC CE1 (%)	60	35	115	22
	Procedure time (min)	315	171	391	26
	TBV processed	2.9	1.4	5.8	26
	Platelet decrease (%)	46	-86	58	23
	Platelet CE1 (%)	19	13	38	23
	AC ratio	12	9	16	26
	Flow rate (mL/min)	54	39	90	26
Neutrophil Recovery	Days to ANC500	12	10	14	26
	Difference from COBE® Spectra Apheresis System historical control (days)	0	-1	2	26

Notes:

- Patients mobilized per institutional standard of practice
- The majority of patients (21 of the 26) underwent a single MNC collection
- Granulocyte % measured by manual differential
- Neutrophil recovery 95% confidence limits (median difference in days regarding historical controls): 0.0
- Collection efficiency CE1 = $\frac{\text{cells collected}}{\text{cell average concentration} \times \text{blood processed}}$
- Collection efficiency CE2 = $\frac{\text{cells collected}}{\text{cell initial concentration} \times \text{blood processed}}$

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