FRESENIUS KABI

A prospective evaluation of unstimulated donor collections for use in adoptive immunotherapy

Amicus Separator

- Amicus had high collection efficiencies for all cell types
- Cross-cellular contamination was low with Amicus
- Amicus had significantly lower donor platelet loss when compared to Optia

Study Parameters

- Comparative evaluation of different continuous flow apheresis devices
- Subjects were healthy, non-cytokine stimulated donors
- Data was collected to analyze product quality, collection efficiency, cross-cellular contamination and donor response

Key Outcomes

- Amicus delivered high collection efficiencies for all cell types*
- Cross-cellular contamination was low on Amicus
- Donor platelet loss was significantly lower on Amicus
- No serious adverse events were reported

*Amicus is cleared for MNC collection. Further analysis was performed on collected MNC product using multiparameter flow cytometry; results may vary depending on analysis method.

Table 1

Amicus delivered high collection efficiencies for all cell types

HIGH COLLECTION EFFICIENCIES				
Cells	**Measure**	**AMICUS** (n=12) Mean ± SD	**OPTIA** (n=20) Mean ± SD	**P-value**
CD45+	Yield (x10⁹)	5.87 ± 1.16	5.66 ± 1.87	0.620
	CE (%)	**24.5 ± 4.81**	**18.3 ± 6.38**	**0.012**
CD34+	Yield (x10⁶)	6.94 ± 3.47	8.22 ± 6.71	0.543†
	CE (%)	**63.7 ± 14.9**	**55.4 ± 18.9**	**0.495**
CD3+	Yield (x10⁹)	2.80 ± 1.00	2.36 ± 0.96	0.169
	CE (%)	**69.4 ± 7.28**	**44.4 ± 17.6**	**<0.001**
CD14+	Yield (x10⁹)	1.20 +/- 0.37	1.64 +/- 0.70	0.002
	CE (%)	**66.8 +/- 17.6**	**67.1 +/- 16.4**	**0.221**

† Differences between apheresis devices used the dependent two-sample t-test for normally distributed data and the Wilcoxon signed-rank test for non-normal distribution.

Table 2

Cross-cellular contamination was low with Amicus

LOW CROSS-CELLULAR CONTAMINATION				
Cells	**Measure**	**AMICUS** (n=12) Mean ± SD	**OPTIA** (n=20) Mean ± SD	**P-value**
PLTs	Yield (x10⁹)	46.2 ± 14.7	114 ± 48.3	<0.001
	CE (%)	**3.55 ± 1.31**	**8.25 ± 4.77**	**0.009†**
RBCs ‡	Yield (x10⁹)	53.0 ± 15.1	16.8 ± 7.44	0.002†
	HCT	9.6 ± 2.6	3.1 ± 0.7	<0.001

‡ The maximum RBC volumes on Amicus and Spectra Optia were 7.5 and 4.0 mL, respectively.

Source: Steininger PA, Strasser EF, Weiss D, Achenbach S, Zimmerman R, Ekstein R. First comparative evaluation of a new leukapheresis technology in non-cytokine-stimulated donors. Vox Sanguinis 2013: DOI 10.1111VOX. 12102.

Refer to Amicus Operator's Manual for a full list of warnings and cautions associated with the use of the Amicus device.

This marking reflects compliance with the applicable CE Marking requirements for medical devices. CE 0123

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