

Evaluation of the Amicus Extracorporeal Photopheresis (ECP) System in Healthy Human Subjects

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BACKGROUND: A new protocol has been developed on the Amicus Separator that enables the devices to perform ECP procedures. The Amicus Separator is used with the Phelix Photoactivation Device, single-use disposable kit, and 8-MOP to provide ECP therapy in a closed system. The objective of this study was to evaluate the safety and performance of the investigational Amicus ECP System in healthy human subjects.

METHODS: The subjects were connected to the ECP kit and the Amicus Separator was programmed to process either 500, 2000, or 4000 mL of ACD-A anticoagulated whole blood (WB) using a 12:1 WB:AC ratio. During MNC collection, samples from the return line were evaluated for plasma hemoglobin, C3a, C5a, and Factor VIII activity.

After MNC collection was complete, the Separator automatically added saline to dilute the collected MNCs. The subjects were then disconnected from the device.

3.4 mL of 8-MOP (20 µg/mL) was added to the treatment container (approx. 200 mL volume) that was subsequently photoactivated with 1.5 J/cm² of UVA light under constant agitation and temperature monitoring in the Phelix Photoactivation Device.

The Amicus Separator reinfused the treated cells and residual kit contents into a transfer pack container to simulate reinfusion to a patient.

In vitro assays were performed on subject WB, return line, collected MNCs, treated MNCs, and re-infused cells. Lymphocyte and monocyte apoptosis were assessed in cultured cells up to 3 days post ECP treatment as well as lymphocyte proliferation after 72 hours of culture.

RESULTS: Mean pre-procedure subject laboratory values were within acceptable ranges. No clinically significant deviations from normal values were noted. All 17 ECP procedures (12 male, 5 female) were safely completed; no AEs were reported. Data presented below are for all procedures (n = 17) or by target WB processed (500 mL: n = 5; 2000 mL: n=6; 4000 mL: n=6).



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Procedure Results	Mean (SD)
Procedure Time (min)*	
500 mL	74 (11)
2000 mL	92 (7)
4000 mL	114 (4)
WB Processed (mL)**	
500 mL	511 (2)
2000 mL	2010 (9)
4000 mL	4017 (6)
AC to Subject (mL)	
500 mL	53 (1)
2000 mL	172 (4)
4000 mL	323 (16)
MNC Collection Efficiency (%)	
500 mL	76 (19)
2000 mL	66 (9)
4000 mL	63 (5)
Saline to Subject (mL)	
	207 (8)
Photoactivation Time (min)	
	21 (2)

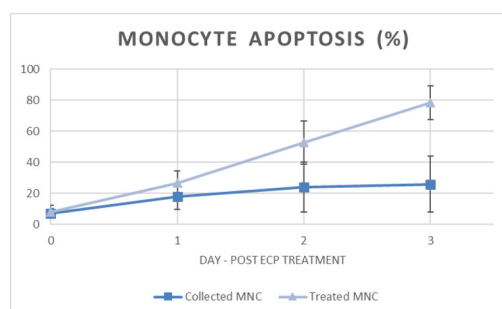
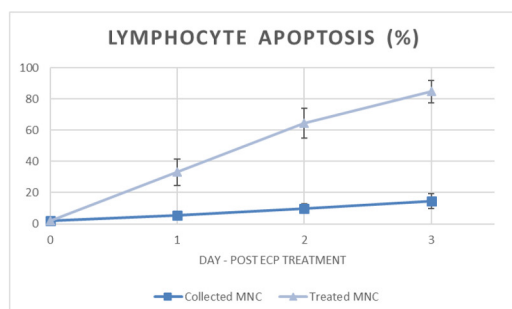
Collection Results	Mean (SD)
WBC (x10⁹)	
500 mL	0.9 (0.2)
2000 mL	2.6 (0.6)
4000 mL	5.0 (0.8)
Lymphocyte (%)	
500 mL	68 (12)
2000 mL	76 (12)
4000 mL	78 (3)
Monocyte (%)	
500 mL	17 (6)
2000 mL	18 (11)
4000 mL	17 (3)
Hematocrit (%)	
500 mL	2.7 (0.1)
2000 mL	2.5 (0.1)
4000 mL	2.0 (0.1)
Platelets (x10³/μL)	
500 mL	119 (39)
2000 mL	91 (20)
4000 mL	98 (28)

* Includes photoactivation and reinfusion

** Includes AC

Overall mean values for WBC, RBC, platelet counts and Hct were comparable for the collected and treated MNCs. Mean values for plasma hemoglobin, C3a, C5a, and Factor VIII activity in the return line and reinfused cells were low and as expected.

Trends for lymphocyte and monocyte apoptosis/viability during culture were similar to reports for other photopheresis systems; a majority of lymphocytes and monocytes were apoptotic 48 hours post ECP treatment. Collected MNCs showed significant levels of lymphocyte proliferation after 72 hours (mean = 61.5%), while lymphocyte proliferation in the treated MNCs was negligible (mean = 1.3%). The mean inhibition of lymphocyte proliferation was 97.85% with all values above 90%.



NOTE: The Amicus ECP System has obtained CE mark approval for the indication of CTCL in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment. Amicus ECP is not cleared for the United States market.