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Congress Abstract

Apheresis-Based Leukapheresis as a Key Step in CAR-T Cell Manufacturing: First Experience in Kazakhstan

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Introduction: CAR-T cell therapy is the newest and most effective treatment method for resistant forms of B-cell hematological malignancies; however, it has until now remained unavailable in Kazakhstan. The first and critically important step in the manufacturing of CAR-T products is apheresis-based leukapheresis — a procedure that determines the quality of the starting cellular material for genetic modification of T lymphocytes. In the Republic of Kazakhstan, this procedure was performed within the framework of a national scientific and technical program for the implementation of CAR-T therapy.

Objective: To study the parameters of apheresis-based leukapheresis and to characterize the cellular composition of the obtained mononuclear cell concentrate in order to assess its suitability as starting material for the manufacturing of CAR-T products.

Materials and Methods: At the Department of Cell Technologies of the Scientific and Production Center of Transfusiology (Astana), 12 leukapheresis procedures were performed in 7 healthy donors and 5 patients with oncohematological diseases. An automated separator Spectra Optia (Terumo BCT, USA) was used with the Mononuclear Cell Collection program. The volume of processed blood, procedure duration, product cellularity, $CD3^+$ T-cell content, and sterility were assessed.

Results: All 12 procedures were completed without complications. The mean volume of processed blood was 9549.5 mL (1.0–2.6 blood volumes), and the mean duration was 230.8 min. Cell yield varied: total leukocyte count ranged from 6.5×10^9 to 32.1×10^9 (mean $14.4\pm8.0\times10^9$), and $CD3^+$ T-lymphocyte content ranged from 129.1×10^7 to 1629.7×10^7 cells per dose. Products from all participants were sterile and deemed suitable for CAR-T cell manufacturing. Differences were noted between the donor and patient groups; however, due to the small sample size, statistical analysis was not performed.

Conclusions: Apheresis-based leukapheresis yields a cellular concentrate that fully meets the requirements for initiating the manufacturing of CAR-T products. This work represents the first standardized protocol in Kazakhstan for obtaining clinically significant cellular material for CAR-T cell manufacturing and lays the foundation for the development of national quality criteria.

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Keywords: CAR-T Cell Therapy; Apheresis-Based Leukapheresis; Mononuclear Cells; $CD3^+$ Lymphocytes; Onomatology