A Novel Cord Blood Collection Device Results in High Harvesting Cell Yield and Ensures Maximal Quality: Results Clinical Trials.

Key Words: Cord Blood; Total Nucleated Cells (TNC); Hematopoietic Stem Cells; Cord Blood Collection; Cord Blood Collection Yield, Cord Blood Bank; Viability.

Abstract

Umbilical Cord Blood (UCB) is being increasingly used as a Stem Cell (SC) source for Transplantation.

Harvested CB derived TNC (Total Nucleated Cells) is the most critical factor in determining speed of engraftment and survival rates post UCBT.

Today, CB is collected by inserting a needle into the Cord's vein and draining into blood donor bags, in a so called "Closed Circuit" procedure where gravitation plays a major role.

SituGen has developed a novel harvesting technology based on a disposable device (The SituGen device from SituGen Ltd. www.situgen.com) – emulating an "Open Circuit" collection in a fully hermetically closed and sterile procedure. The SituGen device is suitable for the needs and requirement as defined by Public Banks of routinely succeeding to collect: "*At least 60% of the collections exceed 100ml (~11.6 x10^8 TNC)*".

In phase III and IV studies, we were able to demonstrate that the total volume of CB collected by the SituGen device was 118.8ml ± 36.0ml (mean ± SD), range 68.3-193.5 (net volume, excluding anticoagulants). This indicates an increase of 46.4ml, 64% in the yield of CB collections in comparison to the traditional gravitation method of collection, resulting in an 80% decrease of the rate of small units disqualification (<50 ml).

The TNC measured was 15.2x10^8 ±6.4 (mean ± SD), range 4.0-31.6, 84% higher than the reported TNC yield using the current traditional method (8.3x10^8), allowing for an average transplantation to larger pediatric and adults weighing 65-98kg.

The mononuclear cells count (MNC) in the units, was 6.2x10^8 ± 3.0 (mean ± SD), range 1.4-14.0, 90% more than the traditional method collections average of 71.6ml (net volume, excluding anticoagulants).

Viability was measured at 98.7% ± 4.0 % (mean ± SD), range 81%-100%.

The total CD34+ counted was 4.0x10^6 ± 2.4 (mean ± SD), range 0.4-8.9, 43% above the 2.8x10^6 average.

The CD34+/TNC ratio measured in the units was 0.26% ± 0.14% (mean ± SD), range 0.04%-0.57%, within the accepted, range of 0.1%-1%.

No significant affect identified due to disinfection of the collection space using 4% Chlorhexidine Gluconate solution.

No maternal cells were present in any of the units collected by the SituGen device.

The SituGen device enables higher CB harvesting yields which may provide larger pediatric and adult patients a greater probability of finding adequate grafts and therefore a greater chance to achieve a better outcome after UCB Transplantation.

Additionally, Cord Blood Banks have a substantial financial advantage by the higher chance of selling the substantially larger units.

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