Safe and efficient peripheral blood stem cell collection in patients with sickle cell disease using plerixafor

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Supplementary information

Supplementary text 1

Leukapheresis was initiated approximately 4 hours after plerixafor administration using the Spectra Optia (continuous-flow mononuclear cell program) apheresis system (Terumo BCT Inc., Lakewood, CO). All cases used Acid Citrate Dextrose formula A for intra-procedural anticoagulation (initial whole blood to anticoagulant ratio of 12:1) and prophylactic IV calcium infusions. During apheresis, operators went slightly deeper into the buffy coat, targeting a hematocrit of 5-6%.

Adverse events (AEs) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0. All serious AEs were tracked for 30 days, until resolution, or until study completion (10 days after last dose of the study treatment), whichever was later. Separate stopping rules for pain and non-pain related AEs were designed to stop enrollment if data suggested the probability of a grade III AE attributable to plerixafor was >20%.

PB CD34+ cells/μL was measured by flow cytometry (BD FACSCanto II, BD Biosciences, San Jose, CA). Cell populations in the collection product were determined by flow cytometry using anti-human CD34 (clone 8G12), CD3 (SK7), and CD19 (SJ25C1) antibodies (BD Biosciences). CD34+ cells were selected using CliniMACS CD34 Reagent System (Miltenyi Biotec, Bergisch Gladbach, Germany).

Supplementary text 2

Of the two participants who required a second apheresis to achieve the minimum CD34+ cell target, baseline CD34+ count/μL was 1.0 and 3.0 CD34+/μL, respectively. Each underwent 15.0

and 15.1 L of processing (day 1) yielding $0.5x10^6$ and $1.2x10^6$ CD34+cell/kg, respectively, and 16.7 and 15.0 L of processing (day 2) to achieve similar collection yields ($0.4x10^6$ and $1.1x10^6$ CD34+cell/kg, respectively), providing a combined total of $0.9x10^6$ and $2.2x10^6$ CD34+cells/kg, respectively. The participant with the highest blood volume processed (30.1 L) achieved $1.8x10^6$ CD34+ cells/kg (baseline CD34+/μL=4.0), whereas the participant with the highest CD34+ cells/kg ($12.0x10^6$) achieved this target after processing 16.7 L (baseline CD34+/μL=12.0). The participant with the highest baseline CD34+ cells/μL (40.1) underwent 15.0 L of processing to achieve a final product of 4.0 $x10^6$ CD34+ cells/kg. Overall this participant's fold increase in CD34+ cell count/μL (1.7) was the lowest of the cohort (7.9, range 1.7-18.0).