

Repeat Peripheral Blood Stem Cell Transplantation for Patients With Sickle Cell Disease and Falling Donor Myeloid Chimerism Levels

NCT04008368

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	National Heart, Lung, and Blood Institute (NHLBI)
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (9)

- Patient with history of SCD or beta thalassemia who previously underwent allogeneic hematopoietic stem cell transplantation (HSCT)
 - Patient with recurrent SCD defined as HbS greater than or equal to 50% for donors with sickle cell trait and greater than or equal to 10% for donors with HbAA with recurrent clinical manifestations (for example but not limited to recurrent painful crises, acute chest syndrome, priapism, or severe anemia) or patients with recurrent beta thalassemia defined as clinical manifestations such as transfusion-dependence or evidence of extramedullary hematopoiesis. The HbS requirement may be waived by the PI or designee for reasons such as the patient is requiring chronic transfusion therapy or otherwise meets clinical criteria for return of SCD.
 - Persistent donor chimerism levels
 - Age greater than or equal to 4 years
 - Negative beta-HCG
- ... and 4 more (see full listing online)

Exclusion (9)

- ECOG performance status of 3 or more or if <16 years of age Lansky score of 50 or lower.
 - Evidence of uncontrolled bacterial, viral, or fungal infections (currently taking medication and progression of clinical symptoms) within one month prior to signing the consent
 - Patients with fever or suspected minor infection should await resolution of symptoms before signing the consent
 - Major anticipated illness or organ failure incompatible with survival from PBSC transplant
 - Pregnant or breastfeeding
- ... and 4 more (see full listing online)

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States

<https://clinicaltrials.gov/study/NCT04008368>

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