

131I-apamistamab-based Conditioning for Hematopoietic Stem Cell Transplant (HSCT) in Advanced Sickle Cell Disease (SCD)

NCT07015684

Status	RECRUITING
Phase	Phase 1
Sponsor	Columbia University
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (24)

- Availability of an HLA-matched sibling donor
- Patients with sickle cell anemia (Hb SS, S⁰thalassemia or severe SC) who are 12 - 50 years of age inclusive AND who have 1 or more of the following:
- Clinically significant neurologic event (stroke) or any neurological deficit lasting at least 24 hours. Stroke will be defined as a clinically significant neurologic event that is accompanied by an infarct on cerebral MRI or cerebral arteriopathy requiring chronic transfusion therapy.
- History of two or more episodes of ACS in the 2-year period preceding enrollment despite supportive care measures (i.e. asthma therapy and/or hydroxyurea).
- History of three or more severe vaso-occlusive pain crises per year in the 2-year period preceding enrollment despite the institution of supportive care measures (i.e. a pain management plan and/or treatment with hydroxyurea).

... and 19 more (see full listing online)

Exclusion (16)

- Pulmonary dysfunction defined as DLCO (corrected for hemoglobin and alveolar volume) < 40% of predicted OR baseline oxygen saturation of <85% or PaO₂ <70.
- Severe cardiac dysfunction defined as ejection fraction <35%.
- Impaired renal function defined as GFR <40.
- Hepatic dysfunction defined as bridging (portal to portal) fibrosis or cirrhosis of the liver OR transaminases >5x ULN for age.
- Clinical stroke within 6 months of anticipated transplant

... and 11 more (see full listing online)

Locations (1 total)

Columbia University Irving Medical Center, New York, New York, United States