A Study to Investigate the Efficacy and Safety of Crizanlizumab (5 mg/kg) Compared With Placebo in Adolescent and Adult Sickle Cell Disease Patients Who Experience Frequent Vaso-Occlusive Crises (SPARKLE)

NCT06439082

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	315 participants

Key Eligibility Criteria

Inclusion (5)

- Participants must be aged 12 years and older on the day of signing informed consent. Adolescents include participants aged 12 to \<18 years old and adults include participants aged 18 years and older.
- Confirmed diagnosis of SCD by Hb electrophoresis or high-performance liquid chromatography (HPLC) (performed locally or by central laboratory if not available locally). All SCD genotypes are eligible.
- Experienced 4 to 12 VOCs (refer to Section 8.3.1 for study definition of VOC) that are HCP-managed (including VOCs leading to management at a health care facility or those managed via remote consultation) within the 12 months prior to the screening visit. Baseline VOCs are determined by medical history and are required to be documented at source.
- If the participant is on HU/HC, they must be taking it for at least 6 months and at stable dose for at least 3 months prior to the Screening visit and plan to continue taking it at the same dose and schedule until at least the participant has reached 52 weeks of the planned study treatment. Participants who have initiated HU/HC 6-12 months prior to the screening visit must have evidence of insufficient control of acute pain despite initiation. These participants must have a cumulative of 4-12 VOCs in the 12 months prior to the screening period, with at least 2 during the last 6 months while on HU/HC. If receiving erythropoietin stimulating agent, the participant must have been receiving the drug for at least 6 months prior to screening visit and plan to continue taking the drug at the same dose and schedule until the participant has reached 52 weeks of the planned study treatment.
- Participants who have not been receiving HU/HC, and/or erythropoietin stimulating agent must not have received it for at least 6 months prior to screening visit.

Exclusion (6)

- Fewer than 4 or more than 12 VOCs that are HCP-managed (including VOCs leading to management at a health care facility or those managed via remote consultation) within the 12 months prior to screening visit as determined by medical history and documented at source.
- History of stem cell transplant and/or gene therapy.
- Received blood products within 30 days prior to Week 1 Day 1 dosing.
- Any documented history of a clinical stroke or intracranial hemorrhage, or an uninvestigated neurologic finding within the past 12 months before screening visit. Silent infarct only present on imaging is not excluded.
- Participating in a chronic transfusion program (pre-planned series of transfusions for prophylactic purposes) and/or planning to undergo an exchange transfusion during the duration of the study; episodic transfusion in response to worsened anemia or VOC is permitted.

... and 1 more (see full listing online)

Locations (30 total)

University Of Alabama, Birmingham, Alabama, United States
Childrens National Hospital, Washington D.C., District of Columbia, United States
University of Florida, Jacksonville, Florida, United States
... and 27 more locations

https://clinicaltrials.gov/study/NCT06439082