Study to Evaluate the Safety and Tolerability of Escalating Doses of Fostamatinib in Subjects With Stable Sickle Cell Disease

NCT05904093

Status	RECRUITING
Phase	Phase 1
Sponsor	National Heart, Lung, and Blood Institute (NHLBI)
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (14)

• Subjects will enroll onto the study and undergo screening. Subjects who do not meet any of the following criteria during screening will not receive the study intervention but will be counted toward study accrual. Screen failures may be rescreened at a later time. In order to be eligible to participate in this study, an individual must meet all of the following criteria:

• Have provided signed written informed consent prior to performing any study procedure, including screening procedures.

• Age between 18-65 years

• Unequivocal diagnosis of SCA (HbSS or HbSBeta\^0) confirmed by hemoglobin electrophoresis performed on patients at least 60 days after a blood transfusion if previously transfused.

• No transfusion in the 60 days prior to signing consent, or absence of Hb A on hemoglobin analysis (by high-performance liquid chromatography; HPLC)

... and 9 more (see full listing online)

Exclusion (17)

• An individual who meets any of the following criteria will be excluded from participation in this study:

• Pain crisis requiring parenteral treatment within 14 days of signing consent.

• Have a significant medical condition that confers an unacceptable risk to participating in the study, and/or that could confound the interpretation of the study data. Such significant medical conditions include, but are not limited to the following:

• History of neutropenia (benign ethnic neutropenia and/or acquired neutropenia related to drug suppression by hydroxyurea and/or cyclic hematopoiesis are permitted).

• History of posterior reversible encephalopathy syndrome (PRES)

... and 12 more (see full listing online)

Locations (1 total)

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