

Effectiveness of Nontraditional Hydroxyurea Algorithms: Novel and Clinical Evaluations (ENHANCE)

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 month(s) and over

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Diagnosis of sickle cell anemia (HbSS) or sickle- β 0-thalassemia (HbS β 0)
- Age 6 months at the time of enrollment
- Clinical decision by patient, family, and healthcare provider to initiate hydroxyurea therapy

Exclusion Criteria:

- Current treatment with regularly scheduled blood transfusions
- Sickle-hemoglobin C disease (HbSC), sickle- β +-thalassemia (HbS β +))

Conditions & Interventions

Interventions:

DRUG: PK-optimized oral hydroxyurea at MTD until 15 years of age.

Conditions:

Sickle Cell Anemia (HbSS), Sickle- β 0-thalassemia (HbS β 0)

Keywords:

sickle cell anemia, SCD, sickle cell, hydroxyurea

More Information

Description:

The main reason for this research study is to learn more about hydroxyurea and the treatment of sickle cell anemia (SCA). Hydroxyurea is a medication that has been studied for many years and has been shown to provide benefits for people with SCA. In this research study, the investigators hope to learn more about how to improve the dosing and monitoring of hydroxyurea and learn more about the long-term effects of hydroxyurea over time. Hydroxyurea is usually dosed based only on your weight. Our study will use a new way to select a starting dose that is based on how each patient absorbs hydroxyurea.

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Principal Investigator ID:

Phase: PHASE4

IRB Number:

System ID: NCT07177300

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