Zinc Supplementation in Sickle Cell Disease: A Precursor to the Think Zinc for Bones Trial

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 15 years to 40 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age: ≥ 15.0 to ≤ 40.0 years
- Diagnosis: SCD-SS or SCD-S Beta zero Thalassemia, in steady state (defined as a minimum of 2 weeks days following pain crisis)
- Male or Female

Exclusion Criteria:

- Taking any supplement containing zinc and unable/willing to stop for 3 months prior to study start
- 25-Hydroxy Vitamin D < 20 ng/mL
- On chronic transfusion therapy (defined as >8 Transfusions/year) and iron overloaded (defined as liver iron concentration > 7 mg/g OR average serum ferritin >4000 ug/L)
- Unable swallow pills or take daily supplement as instructed
- Currently participating in another investigational drug trial
- Prior diagnosis of chronic kidney disease (eGFR < 30 mL/min/1.73m2)

Conditions & Interventions

Interventions:
DRUG: 25 mg/day zinc, DRUG: 40 mg/day zinc
Conditions:
Sickle Cell Disease

More Information

Description:
The goal of this short term prospective Phase II study is to compare the effects of two alternate daily doses of zinc (25 and 40 mg/day) in 34 randomly assigned homozygous Sickle Cell Disease (SCD-SS) patients aged 15-40 years old. The main question it aims to answer is: Which biomarkers are most responsive to zinc supplementation, and what is the maximum tolerated zinc dose that induces the desired changes in biomarkers of bone turnover? Participants will be recruited from 6 American Society Hematology Research Collaborative SCD Centers. Eligible SCD subjects will be invited to participate in the 16-week study, involving 2 baseline blood draws 4 weeks apart, followed by a 12-week zinc intervention. The findings from this study will be used to determine the dosage of zinc to be used in a larger, future study on the long term impact of zinc supplementation on bone health in SCD-SS.

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