Ferric Citrate and Chronic Kidney Disease in Children

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Ages 6 to 18 years (inclusive);
2. Estimated Glomerular Filtration Rate (GFR) of 15-59 ml/min per 1.73 m2 by modified Chronic Kidney disease in Children (CKiD) under 25 (U25) formula;56
3. Serum phosphate <=5.9 mg/dl;
4. Serum ferritin <500 ng/ml and TSAT <50%;
5. For those patients treated with growth hormone, calcitriol, nutritional vitamin D, iron, and/or erythropoiesis-stimulating agents (ESAs) such treatments must have stable dosing for at least 2 weeks prior to screening;
6. Able to swallow tablets;
7. Able to eat at least two meals a day;
8. In the opinion of the investigator, willing and able to follow the study treatment regimen and comply with the site investigator's recommendations.

Exclusion Criteria:

1. Patients currently treated with phosphate binders.
2. History of allergy to all ingredients (including non-medical ingredients) in both products (i.e. investigational product and placebo)
3. Current intestinal malabsorption, documented in the medical record; disease, inflammatory bowel syndrome, and/or Crohn's Disease.
4. Anticipated initiation of dialysis or kidney transplantation within 6 months
5. Current or planned future systemic immunosuppressive therapy
6. Prior solid organ transplantation
7. Receipt of bone marrow transplant within two years of screening
8. Current pregnancy, lactation or female subjects who have reached menarche, unless using highly-effective contraception as outlined in section 7.1.1 of Protocol
9. Patients participating in other interventional study (observational study participation permitted)
10. Poor adherence to medical treatments in the opinion of the investigator
11. Cystinosis
12. Fanconi syndrome
13. Hemochromatosis or laboratory tests indicating possible hemochromatosis or other iron overload (primary or secondary) syndrome

Conditions & Interventions

Interventions:
DRUG: Ferric Citrate, DRUG: Placebo
Conditions:
Chronic Kidney Diseases
Keywords:
Pediatric, CKD, Phosphate Binder

More Information

Description:
We will conduct a 12-month, double-blind, randomized, placebo-controlled trial to assess the effects of therapy with ferric citrate (FC) on changes in intact FGF23 levels (iFGF23, primary endpoint) in 160 pediatric patients (80 in each of the two arms) aged 6-18 years of either sex with chronic kidney disease (CKD) stages 3-4 and age-appropriate normal serum phosphate levels. Participants will be randomized to one of the two groups: 1) FC or 2) FC placebo. Participants will be recruited from 20 core clinical sites.

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