HEART-FID

NCT03037931

Principal Investigator: Dr. Naveed Akhtar, MD (Covenant)

Condition: Heart Failure, Iron-deficiency

Drug: Ferric carboxymaltose vs. Placebos

Official Title: A Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Injectafer® (Ferric Carboxymaltose) as Treatment for Heart Failure With Iron Deficiency

Sponsor: Luitpold Pharmaceuticals

Purpose: The primary objective of this study is to determine the efficacy and safety of iron therapy using intravenous (IV) ferric carboxymaltose (FCM), relative to placebo, in the treatment of participants in heart failure with iron deficiency and with a reduced ejection fraction.

Inclusion Criteria:

1. Adult (≥18 years of age) able to provide informed consent.
2. Stable heart failure (NYHA II-IV) on maximally-tolerated background therapy (as determined by the site Principle Investigator) for at least 4 weeks with no dose changes in heart failure drugs during the last 2 weeks.
3. Able and willing to perform a 6MWT at the time of randomization.
4. Reduced left ventricular ejection fraction. Assessment must be performed at least 12 weeks after major cardiac surgical intervention including coronary artery bypass graft (CABG), valvular repair/replacement, or cardiac resynchronization therapy (CRT) device implantation.
   a. Left ventricular ejection fraction ≤35% obtained during the screening visit OR either of the following i. Historical value of ejection fraction ≤35% within 12 months of screening visit ii. Historical value of ejection fraction ≤25% within 24 months of screening visit
5. Hemoglobin >9.0 g/dL and <13.5 g/dL (females) or <15.0 g/dL (males).
6. Serum ferritin <100 ng/mL or 100 to 300 ng/mL with TSAT <20%.
7. Either documented hospitalization for heart failure within 12 months of enrollment or screening visit N-terminal-pro-brain natriuretic peptide (NT-proBNP) >600 pg/ml (or BNP >200 pg/mL) for patients with normal sinus rhythm or NT-proBNP >1000 pg/ml (or BNP >400 pg/mL) for patients with atrial fibrillation. NOTE: NT-proBNP must be used to confirm eligibility for patients taking sacubitril/valsartan.

Exclusion Criteria:

1. Current or planned oral iron supplementation. Iron-containing multivitamins (<30 mgs /day) are permitted.
2. Known hypersensitivity reaction to any component of FCM.
3. History of acquired iron overload, or the recent receipt (within 3 months) of erythropoietin stimulating agent, IV iron therapy, or blood transfusion.
4. Acute myocardial infarction, acute coronary syndrome, transient ischemic attack, or stroke within 3 months of enrollment.
5. Uncorrected severe aortic stenosis, severe valvular regurgitation, or left ventricular outflow obstruction requiring intervention.
6. Current atrial fibrillation or atrial flutter with a mean ventricular response rate >100 per minute (at rest).
7. Current or planned mechanical circulatory support or heart transplantation.
8. Hemodialysis or peritoneal dialysis (current or planned within the next 6 months).
9. Documented liver disease, or active hepatitis (i.e. alanine transaminase or aspartate transaminase >3 times the upper limit of normal range).
10. Current or recent (within 3 years) malignancy with exception of basal cell carcinoma or squamous cell carcinoma of the skin, or cervical intraepithelial neoplasia.

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Exclusion Criteria (Continued):

11. Known gastrointestinal bleeding. Patients with screening ferritin <15ng/ml must have an appropriate evaluation within 3 months of screening.
12. Female participant of child-bearing potential who is pregnant, lactating, or not willing to use adequate contraceptive precautions during the study and for up to 5 days after the last scheduled dose of study medication.
13. Inability to return for follow up visits within the necessary windows

Source: https://clinicaltrials.gov/ct2/show/NCT03037931
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