

Details of Ongoing Studies

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STUDY	INCLUSION CRITERIA	IRON INTERVENTION	PRIMARY OUTCOME
Intravenous Iron in Patients With Systolic Heart Failure and Iron Deficiency to Improve Morbidity & Mortality. FAIR-HF2 , (n=1200) (NCT03036462)	HF, confirmed iron deficiency, Hb 9.5-14.0 g/dL	FCM (1,000 mg, then 500- 1,000 mg within 4 weeks [max 2,000 mg total], then 500 mg every 4 months	HF hospitalizations and CV death (composite endpoint)
Effect of IV Iron (Ferric Carboxymaltose) on Exercise Tolerance, Symptoms and Quality of Life in Patients With HFpEF and Iron Deficiency With and Without Anemia. FAIR-HFpEF , NCT03074591 (n=200)	HF with preserved LVEF (HFpEF) and diastolic dysfunction, LVEF \geq 45%, NYHA II-III, either HFH within 1 year or elevated NP, Hb $>$ 9.0 g/dL and \leq 14.0 g/dL, ferritin $<$ 100 μ g/L or ferritin 100-299 with TSAT $<$ 20%, 6MWD $<$ 450 m	FCM vs placebo	Exercise capacity: change in 6MWD from baseline to 12 months
Impact of Intravenous Iron Repletion on Mechanisms of Exercise Intolerance in HFpEF. IRONMET-HFpEF (NCT04945707), n = 66	NYHAII-IV; EF \geq 50%; NT-proBNP $>$ 125ng/L or PCWP $>$ 15 mmHg(rest) or PCWP/CO ₂ (exercise) or HF hospitalization within 12 months; Hgb 9-15g/dL (males); Hgb 9.0 - 13.5g/dL (females); pVO ₂ \leq 75% predicted	Ferric Derisomaltose 1000mg vs. placebo	Change in peak oxygen uptake (peak VO ₂) from baseline to week 12 in HFpEF subjects with functional iron deficiency
The Prevalence of Iron Deficiency and the Effectiveness of Ferinject® in Patients With HFpEF. ID-HFpEF (NCT05793996), n = 100	NYHAII-IV; EF \geq 50%; ID (ferritin below 100 μ g/L, or below 300 μ g/L when transferrin saturation (TSAT) is below 20%; hemoglobin (Hb) at the time of switching on (90-150 g/l)	Ferric carboxymaltose vs. diet therapy without drug therapy vs. no intervention	Change of 5 or more points on the Kansas City Cardiomyopathy Questionnaire (KCCQ) (0-100 points) + change in test distance with a 6-minute walk (6MWD - 150 meters or more) by 35 meters or more.
The Effects of Ferric Derisomaltose in Patients With Acute Heart Failure and Iron Deficiency on Exercise Capacity and Quality of Life. COREVIVE-HFrEF (NCT05971732), n = 146	Patients with HFrEF (EF \leq 50%); currently hospitalized for an episode of acute HF, NYHA II-IV; with ID (ferritin $<$ 100 ng/mL or ferritin 100-299 ng/mL and TSAT $<$ 20%)	Ferric derisomaltose vs. placebo	Difference of 6-minute walking distance in meters from baseline to day3 after IV iron injection.
Effect of INtravenous FERRic Carboxymaltose Onmortality and Cardiovascular Morbidity, and Quality of Life in Iron Deficient Patients With Recent Myocardial infarction. INFERRCT (NCT05759078), n = 2000	Patients with HFrEF (EF \leq 50%); diagnosis of acute myocardial infarction (STEMI or NSTEMI) up to 4 weeks before randomization; and with iron deficiency (TSAT $<$ 20% and/or serum ferritin $<$ 100 ng/mL)	Ferric carboxymaltose vs. placebo	<ul style="list-style-type: none"> • Time to CV death • Number of HF events • Time to first HF event • Change in quality of life

ADAPTED FROM:

- Beavers CJ et al. "Iron deficiency in heart failure: a scientific statement from the Heart Failure Society of America." Journal of Cardiac Failure 29.7 (2023): 1059-1077.
- ClinicalTrials.gov