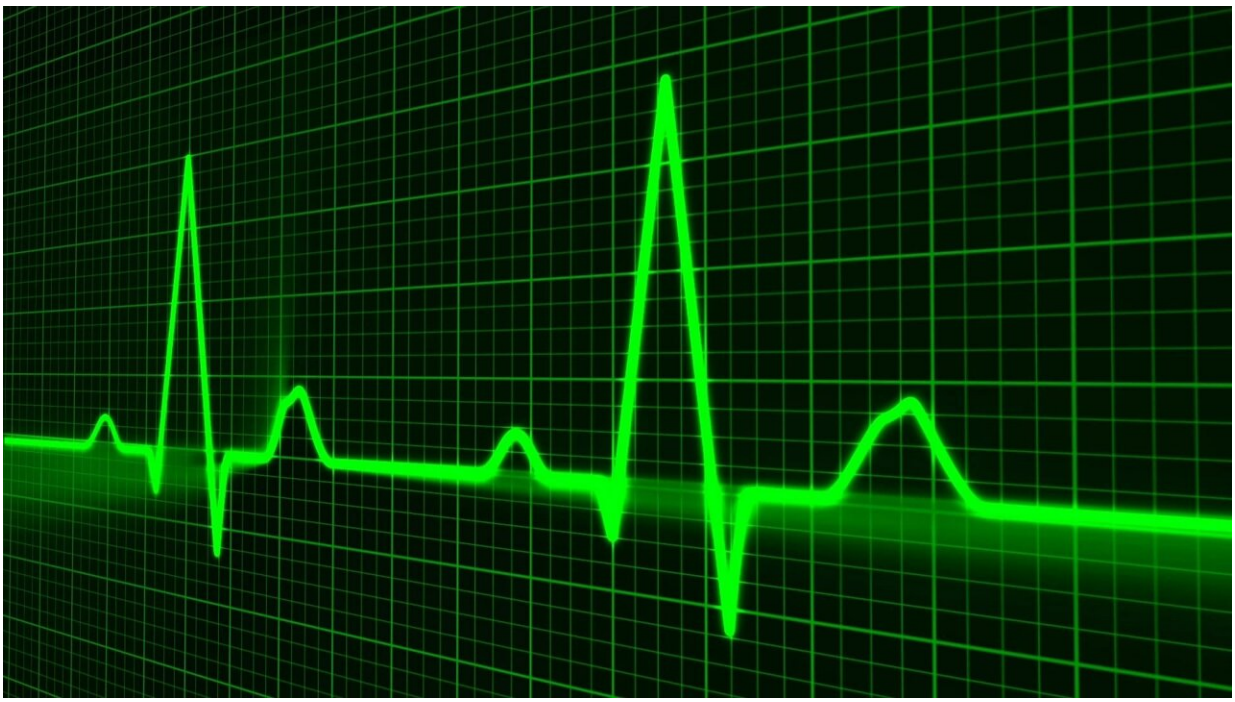
HEART-FID trial finds no significant benefit from ferric carboxymaltose in heart failure patient outcomes

August 30 2023, by Justin Jackson



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A trial led by the Duke Clinical Research Institute, Durham, has investigated the long-term safety and efficacy of supplementing heart failure patients with iron.

In a paper, "Ferric Carboxymaltose in Heart Failure with Iron Deficiency," published in the *New England Journal of Medicine*, the team compared intravenous ferric carboxymaltose to placebo and standard heart failure therapy.

There was no significant difference between ferric carboxymaltose and placebo in the primary composite outcome, including death, heart failure hospitalizations, and a six-minute walk distance.

The double-blind, randomized HEART-FID trial consisted of ambulatory patients with heart failure, a left ventricular ejection fraction (LVEF) of 40% or less, iron deficiency, and anemia or lower-than-normal hemoglobin levels. The trial recruited 3,065 patients, of whom 1,532 were randomly assigned to the ferric carboxymaltose group and 1,533 to the placebo group.

Death by month 12 occurred in 131 patients (8.6%) in the ferric carboxymaltose group and 158 (10.3%) in the placebo group. A total of 297 and 332 hospitalizations for heart failure, respectively, occurred by month 12. Repeated dosing of ferric carboxymaltose appeared safe, with an acceptable adverse-event profile compared to the placebo group.

Iron deficiency is common in heart failure patients and is associated with worse symptoms and outcomes. Prior trials showed mixed results regarding the use of intravenous iron therapy in heart failure patients with iron deficiency.

Ferric carboxymaltose is an iron complex that consists of a ferric hydroxide core stabilized by a carbohydrate shell for a controlled delivery of iron to target tissues and is administered intravenously.

The HEART-FID trial aimed to assess the long-term safety and efficacy of ferric carboxymaltose in heart failure patients with iron deficiency.

Unlike some previous studies, this trial did not find a significant reduction in hospitalizations for heart failure with ferric carboxymaltose.

The AFFIRM-AHF trial is mentioned as one of the previous trials. It suggested a reduction in recurrent hospitalizations for heart failure but did not show a significant decrease in cardiovascular mortality with ferric carboxymaltose compared to placebo.

The IRONMAN trial, which assessed a different intravenous iron formulation (ferric derisomaltose), is also discussed. It showed findings similar to those in the AFFIRM-AHF trial, with a reduction in recurrent hospitalization for heart failure but no significant decrease in cardiovascular mortality.

The authors point out that these previous trials occurred during the COVID-19 pandemic, which may have influenced hospitalization rates and outcomes.

More information: Robert J. Mentz et al, Ferric Carboxymaltose in Heart Failure with Iron Deficiency, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2304968