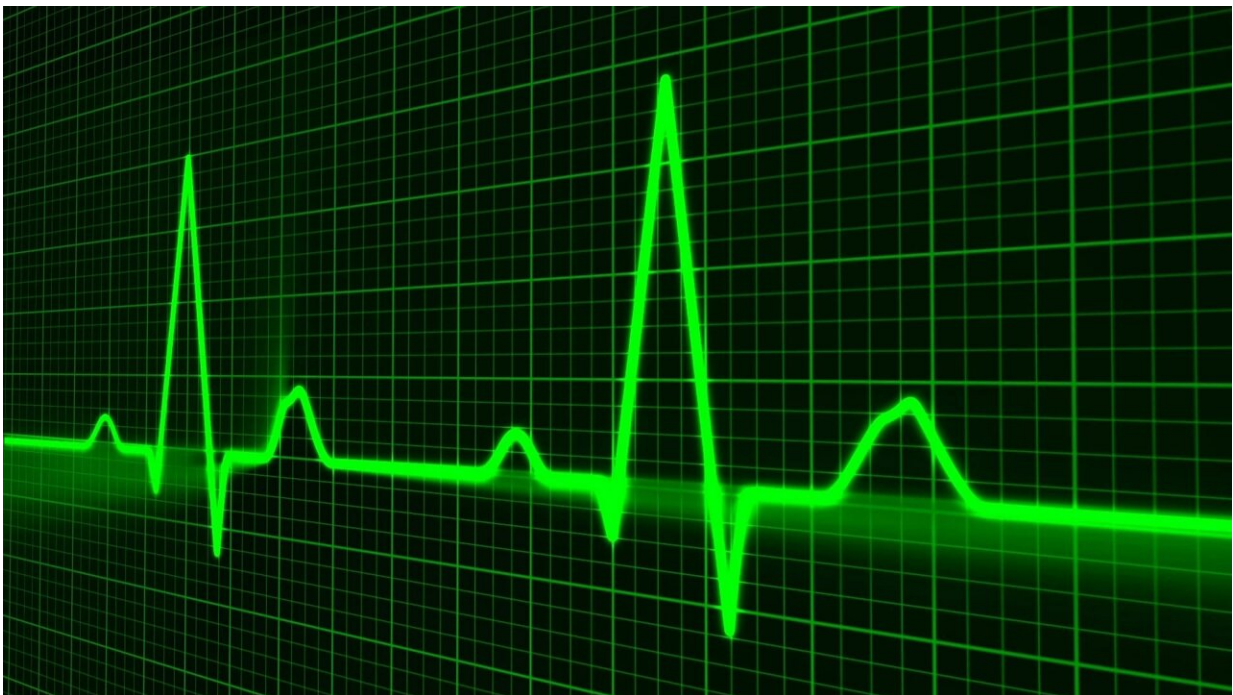


# HEART-FID trial finds no significant benefit from ferric carboxymaltose in heart failure patient outcomes

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](https://doi.org/10.1056/NEJMoa2304968)

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Citation: HEART-FID trial finds no significant benefit from ferric carboxymaltose in heart failure patient outcomes (2023, August 30) retrieved 29 April 2024 from <https://medicalxpress.com/news/2023-08-heart-fid-trial-significant-benefit-ferric.html>

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