IRONMAN adds support for iron repletion in HF

The IRONMAN trial, presented at AHA 2022, adds further support to the known benefits of intravenous (IV) iron therapy in patients with heart failure (HF) with reduced ejection fraction and iron deficiency, but narrowly misses the primary end point of hospitalization for HF and cardiovascular death.

Previous studies had shown the benefits of IV ferric carboxymaltose therapy at 24 weeks of follow-up. The IRONMAN trial aimed to assess the longer-term efficacy and safety of a different iron preparation, ferric derisomaltose, in a broader range of patients. The trial included 1,137 patients with HF, left ventricular ejection fraction ≤45% and iron deficiency, who were randomly assigned to receive IV ferric derisomaltose or usual care. After a median of 2.7 years, IV ferric derisomaltose non-significantly reduced the rate of the primary end point by 18% compared with usual care ($P = 0.070$). However, the trial was affected by the COVID-19 pandemic. “There were substantial periods of time when we couldn’t assess patients in person and see if they had re-developed iron deficiency and re-dose if necessary,” says trial investigator Ian Ford. Therefore, they prespecified a COVID-19 sensitivity analysis. “The data confirmed the negative effect of the pandemic and suggested that the magnitude of benefit of IV ferric derisomaltose was even higher, with a 24% reduction in risk of HF hospitalization and cardiovascular death ($P = 0.047$),” says trial investigator Paul Kalra. The treatment was safe, with no overall excess in serious adverse events and fewer cardiac serious adverse events.

“We believe the results of IRONMAN, building on previous data, demonstrate that correcting iron deficiency with IV iron can improve patient wellbeing and reduce the risk of HF hospitalization in a broad range of patients with HF,” says Ford. “These results are likely to influence clinical practice and guidelines,” adds Kalra.

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