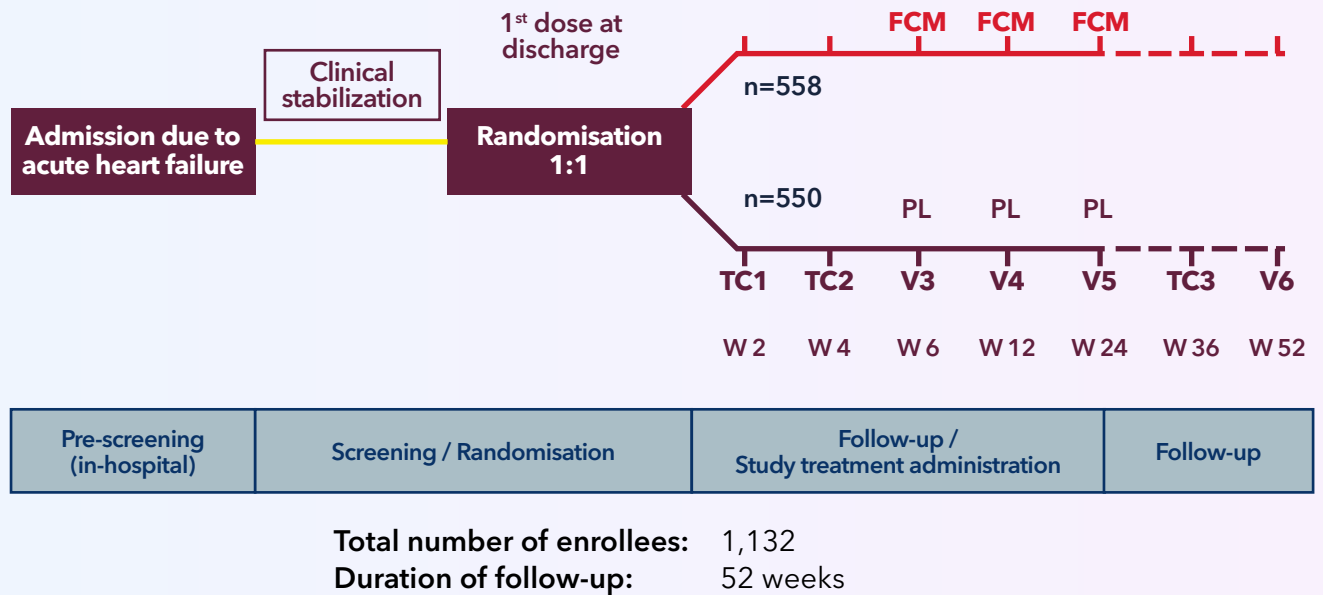


AFFIRM-AHF was designed to assess intravenous ferric carboxymaltose among patients who were hospitalized for acute heart failure and iron deficiency. This was a randomized, parallel, placebo-controlled, double-blind clinical trial done at 121 sites in Europe, South America, and Singapore. The study design is described in the figure below.



Key inclusion Criteria

- Iron deficiency serum ferritin < 100ng/mL or 100-300 ng/mL + TSAT<20%
- LVEF<50%
- Hb 8 - 15 g/dL

Primary outcome:

- A composite of total hospitalizations for heart failure and cardiovascular death up to 52 weeks after randomization.

*occurred in 52.5% of the ferric carboxymaltose group compared with 67.6% of the placebo group

Important Secondary Outcomes:

- Cardiovascular death: occurred in 13.8% of the ferric carboxymaltose group compared with 14.2% of the placebo group (p = 0.809)
- Total heart failure hospitalizations: occurred in 48.9% of the ferric carboxymaltose group compared with 53.5% of the placebo group (p = 0.013)
- Fewer days lost to HF hospitalizations and CV death with FCM compared to placebo (369 days/100 patient years vs. 548 days/100 patient years, p = 0.035)
- Improved HRQoL with FCM vs. placebo

Interpretations:

In iron-deficient patients with heart failure (LVEF <50%), who were stabilized after an acute HF event, treatment with intravenous ferric carboxymaltose was associated with a significant reduction in total heart failure hospitalizations, as well as improved HRQoL compared with placebo.

FCM = FERRIC CARBOXYMALTOSE; PL = PLACEBO; HRQOL = HEALTH-RELATED QUALITY OF LIFE

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