ferinject®
ferric carboxymaltose

AFFIRM-AHF evaluated the impact of Ferinject® (ferric carboxymaltose) treatment of iron deficiency (ID) on outcomes in patients with heart failure (HF) vs placebo[1]

Ferinject® is indicated for the treatment of iron deficiency when:
- Oral iron preparations are ineffective
- Oral iron preparations cannot be used
- There is a clinical need to deliver iron rapidly

The diagnosis of iron deficiency must be based on laboratory tests.[2]

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA YellowCard in Google Play or Apple App Store. Adverse events should also be reported to Vifor Pharma UK Limited (Tel: 01276853633) Email: medicalinfo_UK@viforpharma.com

Click here for prescribing information

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CSL Vifor

AFFIRM-AHF was the first international, multi-centre, double-blind, randomised controlled trial to compare the effect of Ferinject® vs placebo on recurrent hospitalisations and mortality in patients with ID and LVEF <50% stabilised after an episode of acute heart failure (AHF)[1]

Key inclusion criteria

- Iron deficiency (ferritin <100 µg/L, or ferritin between 100-299 µg/L plus transferrin saturation [TSAT] <20%)
- Left ventricular ejection fraction (LVEF) <50%
- Haemoglobin (Hb) 8-15 g/dL

Randomisation 1:1

- Ferinject® n=558
- Placebo n=550

1st dose: at discharge
2nd dose: week 6
3rd dose: week 12 (if ID persists)
4th dose: week 24 (if ID persists)

The study was affected by the COVID-19 pandemic

- A pre-specified pre-COVID-19 sensitivity analysis was conducted, which involved censoring follow-up when the first COVID-19 patient was reported in each country

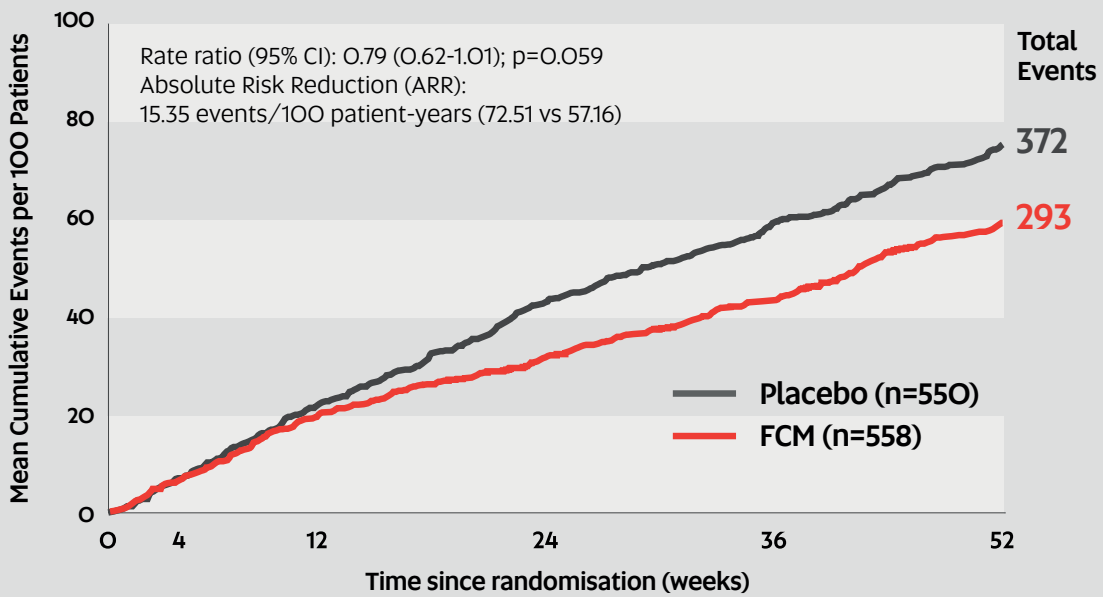
Ferinject® numerically reduced the composite rate of cardiovascular (CV) death and HF re-hospitalisation, but this was not statistically significant[1]

Primary endpoint

The primary endpoint was a composite of total HF hospitalisations and CV death up to 52 weeks of follow-up

The AFFIRM-AHF primary endpoint was not statistically significant (p=O.O59)

Total HF Hospitalisations & CV Death



mITT population.

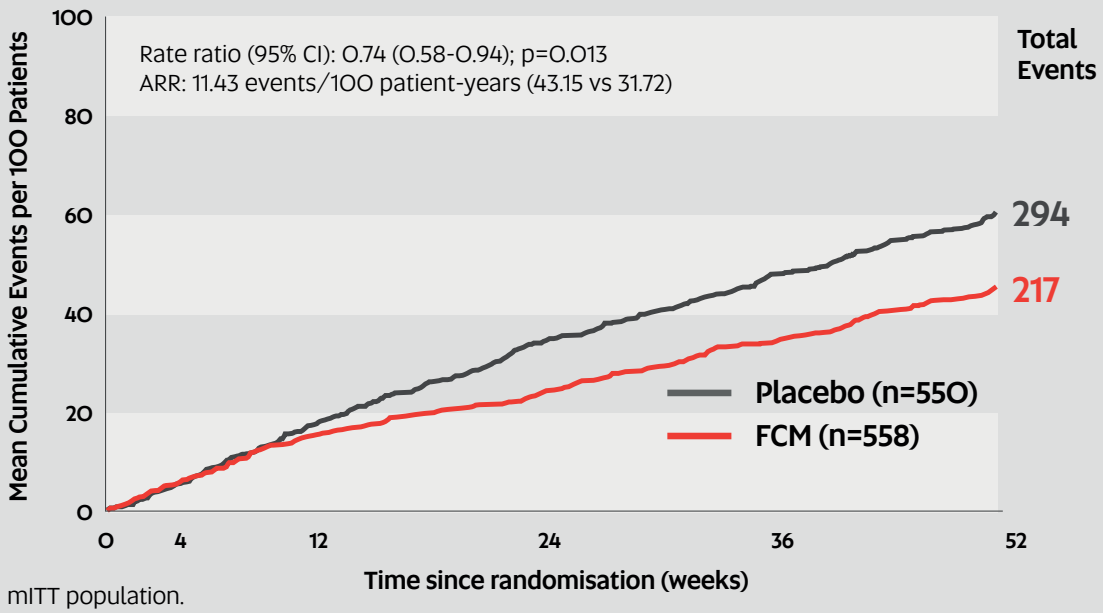
Adapted from Ponikowski et al, 2020.

The numerical effect on the primary endpoint was driven by a 26% reduction in HF re-hospitalisations, with no apparent effect on CV death[1]

Secondary endpoints

Total HF Hospitalisations

Secondary endpoint - component of the primary endpoint **(the primary endpoint was not met)**



mITT population.

Adapted from Ponikowski et al, 2020.

CV death: component of the primary endpoint **(the primary endpoint was not met)**: no apparent difference between groups at 14% (77/558) with Ferinject vs 14% (78/550) with placebo (HR [95% CI]: 0.96 [0.70-1.32]; p=0.81. ARR: 0.2 events/100 patient-years (16.1 vs 15.9).

First HF hospitalisation or CV death: occurred in 32% (181/558) of patients assigned Ferinject and in 38% (209/550) patients assigned placebo (HR: [95% CI]: 0.80 [0.66-0.98]; p=0.030. ARR: 9.7 events/100 patient-years).

Days lost due to HF hospitalisations and CV death: 369/100 patient-years in the Ferinject® group and 548/100 patient-years in the placebo group [ARR 179.4 days/100 patient-years; RR 0.67, 95% CI, 0.47-0.97; p=0.035].

There were 370 total **CV hospitalisation and CV death events** in the Ferinject® group compared to 451 events in the placebo group [ARR 19.09 events/100 patient-years; RR 0.80; 95% CI, 0.64-1.00; p=0.050].[1]

AFFIRM-AHF further added to the well-characterised tolerability profile of Ferinject®[1,2]

Overall incidence of adverse events (AEs), serious AEs, and AEs leading to hospitalisation, withdrawal of treatment, or study discontinuation were similar in the Ferinject® and placebo groups[1]

	Ferinject® group (N= 559)*		Placebo group (N=551)*	
	n, (%)	Total events	n, (%)	Total events
Most frequent reported event - Cardiac disorder events	224 (40.1%)	391	244 (44.3%)	453
AEs leading to discontinuation	98 (17.5%)	117	96 (17.4%)	123
Serious adverse events	250 (44.7%)	547	282 (51.2%)	632

*Safety population

Please refer to the Ferinject® Summary of Product Characteristics for complete tolerability information.

ferinject®
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Ferinject UK Prescribing Information

Ferric Carboxymaltose 50mg iron/mL dispersion for injection/infusion
10ml/5 vials, 20ml/1 vial

Click here or scan the QR code to access UK prescribing information for Ferinject® (ferric carboxymaltose)

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References
1. Ponikowski P, et al. Lancet. 2020; 396: 1895-1904 (and supplementary information). **2.** Ferinject® Summary of Product Characteristics.

AE: adverse event; **AHF:** acute heart failure; **ARR:** absolute risk reduction; **CI:** confidence interval; **COVID-19:** Coronavirus Disease 2019; **CV:** cardiovascular; **FCM:** ferric carboxymaltose; **Hb:** haemoglobin; **HF:** heart failure; **HR:** hazard ratio; **ID:** iron deficiency; **LVEF:** left ventricular ejection fraction; **mITT:** modified intention-to-treat; **RR:** rate ratio; **TSAT:** transferrin saturation.