

# Intravenous ferric derisomaltose versus oral iron for iron deficient pregnant women: a randomised controlled trial

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## Abstract

**Objective:** Compare the efficacy of intravenous ferric derisomaltose (FDI) with oral iron in pregnant women with persistent iron deficiency.

**Design:** Single-centre, open-labelled, randomised controlled trial.

**Setting:** Danish university hospital.

**Population:** Women 14–21 weeks pregnant with persistent iron deficiency (ferritin <30 µg/L).

**Methods:** Allocation to 1,000 mg intravenous FDI (single-dose) or 100 mg elemental oral iron daily (FA). Assessment of blood tests, patient reported outcomes (fatigue and quality of life) and adverse events throughout eighteen weeks' follow-up.

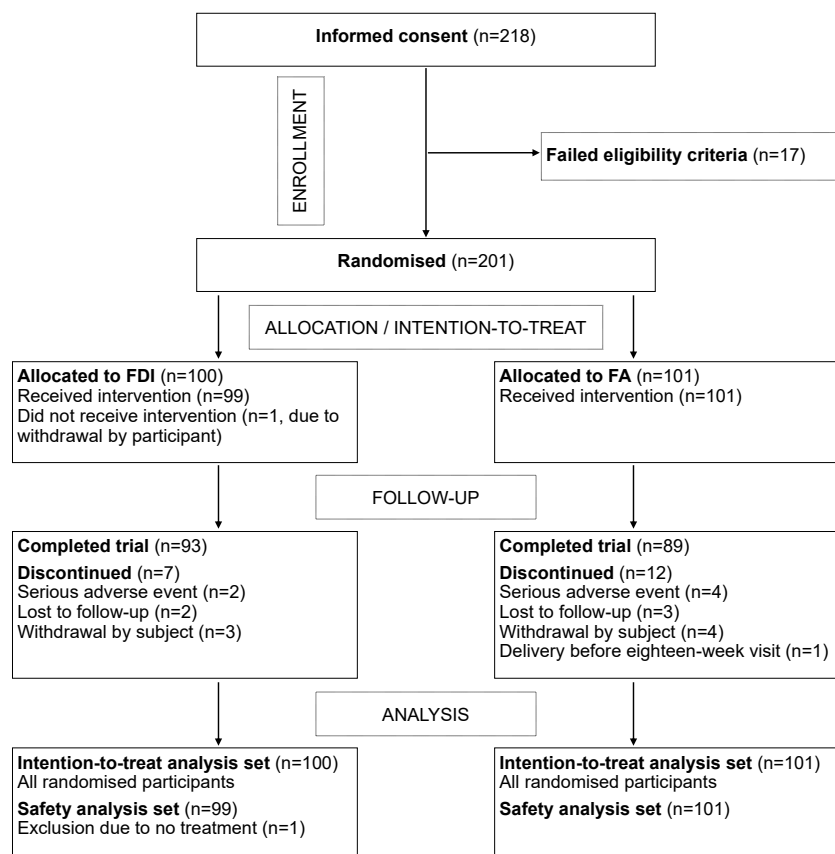
**Main outcome measures:** Proportion of non-anaemic (haemoglobin [?]11 g/dL) women throughout follow-up (primary endpoint), assessed by Kaplan-Meier estimates compared between groups by risk difference analysis. Change in haematological markers and patient reported outcomes, assessed by restricted maximum likelihood estimates compared between groups by a repeated measures mixed model.

**Results:** From July 2017 through February 2020, 100 women were randomised to FDI and 101 to FA. In the FDI vs. FA group 89% vs. 88% were non-anaemic prior to inclusion. Throughout follow-up, 91% vs. 73% were non-anaemic in favor of FDI (18% difference, 95% CI 0.10–0.25, p<0.001). The haemoglobin least-squares mean increase was significantly greater in the FDI vs. FA group at week six (0.4 vs. -0.2 g/dL, p<0.001), twelve (0.5 vs. 0.1 g/dL, p<0.001) and eighteen (0.8 vs. 0.5 g/dL, p=0.01). Improvements in patient reported fatigue and psychological well-being were greater in the FDI group at weeks three and six. The incidence of treatment related adverse events was comparable across treatments.

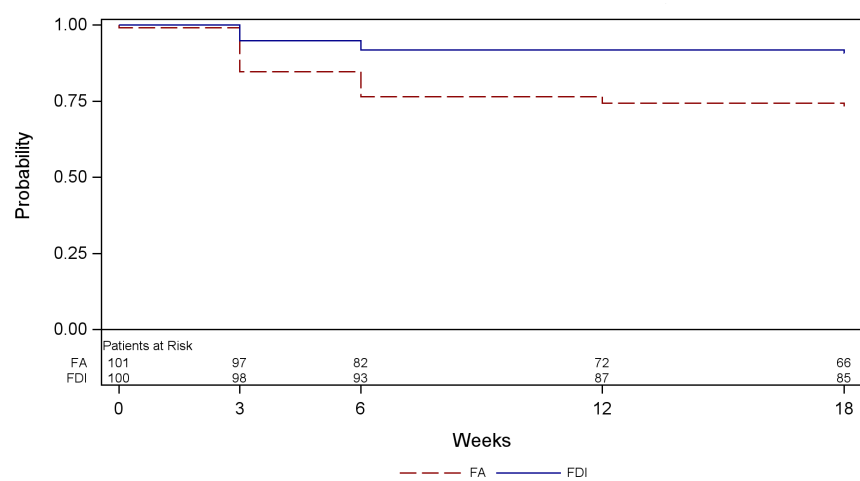
**Conclusions:** FDI was superior for avoiding anaemia compared to oral treatment, and biochemical superiority was accompanied by improved fatigue and psychological well-being.

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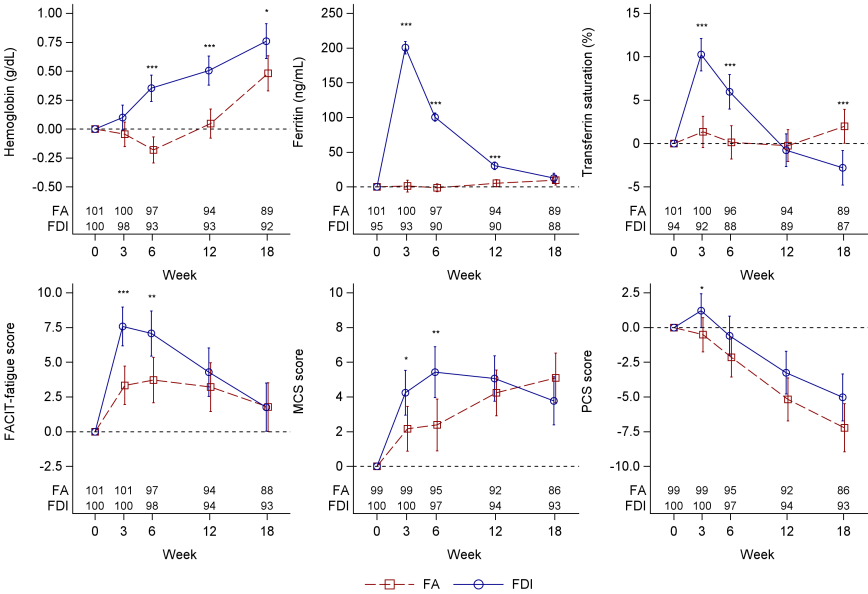
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