Iron deficiency in women of childbearing age with self-reported oral iron gastrointestinal intolerance and management with an oral iron-whey-protein formulation (Active Iron).

PART 1: Screening study (n=204)

Objective: Document prevalence of low iron, iron deficiency and anaemia in women of childbearing age with self-reported history of intolerance to oral iron.

Results: Only **8%** of the women screened recalled a formal diagnosis of iron deficiency or anaemia.

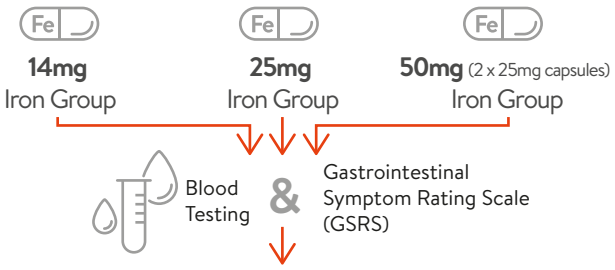
However: **63%** of the women screened had low iron stores (ferritin <30µg/L, with or without anaemia).

32% of the women screened had moderate to severe iron deficiency (ferritin <12µg/L, with or without anaemia).

PART 2: Randomised, double-blind, parallel, group, 3-dose clinical study (n=59)

Objective: Compare compliance, gastrointestinal tolerability and clinical efficacy associated with three different doses of Active Iron in women with a history of intolerance to oral iron.

Method:

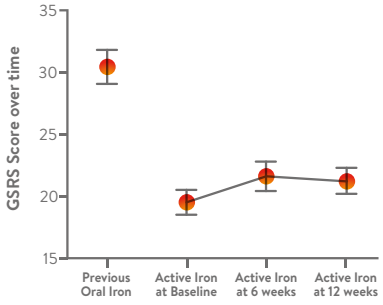


Primary End Point: Clinically proven greater compliance and tolerability

Patients showed **significantly lower** Gastrointestinal Symptom Rating Scale (GSRS) scores on Active Iron compared to previous oral iron (P<0.001).

There were no differences in GSRS between the dose groups during the study (14mg, 25mg and 50mg) and the average GSRS score did not change over the study period.

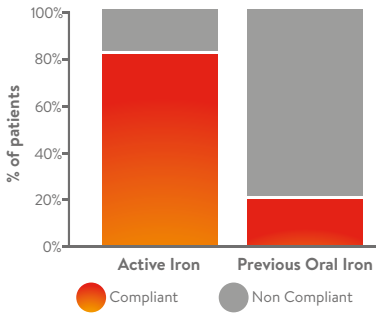
A score of 15 is a perfect GSRS score reflecting no adverse GI symptoms.



80% were classified as compliant with therapy using Active Iron compared to 20% on previous oral iron (p<0.0001).

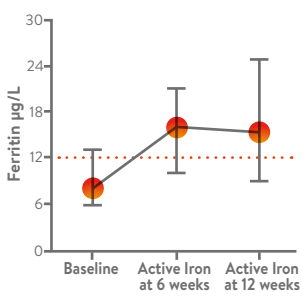
Patients taking Active Iron were **4X** more likely to be compliant versus previous oral iron.

There were no differences in compliance between the dose groups during the study.



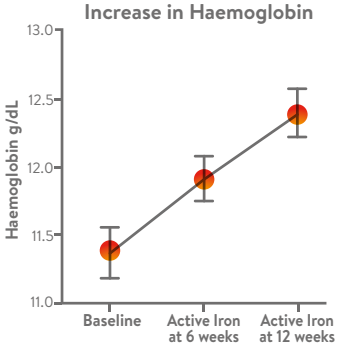
Secondary End Point: Clinically proven to significantly increase iron levels

Increase in Iron Stores



Median ferritin levels in the overall group (14mg, 25mg and 50mg dose groups) increased from 8.00 to 15.5 µg/L, up within 6 weeks and sustained at 12 weeks (**94% increase**, P=0.0002).

Increase in Haemoglobin



Haemoglobin levels in the overall group (14mg, 25mg and 50mg dose groups) increased from 11.36 g/dL to 12.40 g/dL (P=0.0007) over 12 weeks, in patients with anaemia.

Haemoglobin levels were normalised in 75% of patients with anaemia in the 50mg iron group.

Conclusions:

- Low iron, iron deficiency and anaemia are common in women of childbearing age with a history of intolerance to oral iron.

- Active Iron can improve oral iron compliance and tolerability, as well as iron levels in these women.

Ledwidge et al. 2021. Data on File.