<table>
<thead>
<tr>
<th>Study</th>
<th>Trial characteristics</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Dosing schedule</th>
<th>ITT definition</th>
<th>Numbers in trial</th>
<th>Measurements</th>
<th>Duration</th>
<th>Patient characteristics</th>
<th>Oxford quality scores</th>
<th>Withdrawals</th>
<th>Efficacy</th>
<th>FFM</th>
<th>Efficacy</th>
<th>NFK, TSAT, and reticulocytes</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1VT04004</strong> [44]</td>
<td>Open-label, multicentre, randomized, active-control, parallel group study Patients with non-dialysis-dependent CKD who required iron supplementation and baseline Hb level stratification by degree of renal function impairment and baseline Hb level</td>
<td>Criteria for randomization included a hemoglobin ≤ 11.0 g/dL, on two occasions within a 12-month period. TSAT ≥ 25%, ferritin ≤ 300 µg/L, a history of gastrointestinal problems with oral iron. Current treatment for TSAT with non-protocol use of iron was permitted.</td>
<td>Hypersensitivity to ferrous sulphate or FCM use or change in dose</td>
<td>1F0M: 1,000 mg IV over 15 minutes at day 0, with 300 mg on day 17 and/or day 31 if needed, then baseline maximum dose was 15 mg/kg if weight below 66 kg or 325 mg if weight ≥ 66 kg.</td>
<td>ITT-defined as patients who received at least 1 dose of randomized study medication; had stable EPO for at least 8 weeks before randomization, and had no significant changes in baseline hemoglobin assessment, and had NDE-CKD characterized by TSAT ≤ 45 nmol/L in 73 patients.</td>
<td>101 randomized, 100 ITT</td>
<td>Mean Hb increase ≥ 10 g/L at some time during study period</td>
<td>Total phase II, week</td>
<td>All cause</td>
<td>FFM = 131/145</td>
<td>FCM = 10/145</td>
<td>All randomizations = 2</td>
<td>Oral iron = 19/103</td>
<td>Oral iron = 20/145</td>
<td>Oral iron = 0/101</td>
<td>Orally: transmission of FCM = 1 (prostate cancer, trauma)</td>
</tr>
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<td><strong>1VT04005</strong> [44]</td>
<td>Open, non-randomized extension study of 1VT04004 Patient completing 1VT04004 and those discontinuing because of use or change in use of EPO, or nonprotocol use of iron</td>
<td>As 1VT04004 except for treatment with iron</td>
<td>Dosing schedule: depending on previous scheduledvisit results</td>
<td>For TSAT ≥ 20% and ferritin ≥ 233 µg/L, no FCM</td>
<td>For TSAT &gt; 20% and ferritin ≥ 325 µg/L, maximum dose of FCM 1,000 mg (15 mg/kg to 66 kg)</td>
<td>Others, maximum FCM 500 mg (15 mg/kg to maximum 500 mg) administered within one week.</td>
<td>145 enrolled ≥ 12 at least 1 dose FCM in the extension was efficacy ITT 140 with FCM in either trial formed safety ITT</td>
<td>Clinical success - Hb ≥ 11 g/L, TSAT ≥ 30%, ferritin 100-300 µg/L. Sustained success - clinical success on more than 90% of visits. Up to 336 days.</td>
<td>Age - median 66 years (range 20-88)</td>
<td>Women - 67%</td>
<td>Caucasian - 50%</td>
<td>Black - 27%</td>
<td>Other - 16%</td>
<td>All had concomitant medical conditions, and all received concomitant medications.</td>
<td>Baseline</td>
<td>FCM = 64/147</td>
</tr>
</tbody>
</table>
Postpartum anemia and heavy uterine bleeding

<table>
<thead>
<tr>
<th>Event</th>
<th>Oral iron</th>
<th>FCM</th>
<th>Venofer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>58/162</td>
<td>117/139</td>
<td>116/137</td>
</tr>
<tr>
<td>Serious AE</td>
<td>12/162</td>
<td>7/139</td>
<td>8/137</td>
</tr>
<tr>
<td>Death</td>
<td>2/162</td>
<td>0/139</td>
<td>0/137</td>
</tr>
</tbody>
</table>

**Initial baseline values**

- **Hb**: Mean 148 g/L (range 100-160 g/L); ferritin - mean 24 µg/L (range 1-100 µg/L); TSAT - mean 9% (range 2-20%).
- **Women aged 45 years or younger**: 46%, age ≥ 60 years: 54%.

**Inclusion criteria**

- Women aged ≥ 18 years with postpartum anemia (Hb ≤ 100 g/L and/or serum ferritin ≤ 200 µg/L).
- Hypotension: Blood pressure < 100 mmHg systolic or < 60 mmHg diastolic.
- Hemodynamics: Positive fluid challenge.

**Exclusion criteria**

- Women with other types of anaemia.
- Women with significant recent vaginal bleeding.
- Women with a history of heavy menstrual bleeding.
- Women with a history of gastrointestinal bleeding.
- Women with a history of recent treatment with investigational drugs.

**Study design**

- Open-label, multicentre, randomized, active-controlled, parallel-group study.
- Postpartum anemia in delivery and 45 days postpartum.
- Women aged ≥ 18 years with postpartum anemia (Hb ≤ 100 g/L and/or serum ferritin ≤ 200 µg/L).

**Dosing regimen**

- Oral iron: 137 ± 8 g/L.
- FCM: 23 ± 17%.
- Venofer: 20 ± 12%.

**Endpoints**

- Hemoglobin responder (≥ 10 g/L at 4 weeks).
- Maximum marrow iron increase of ≥ 10 g/L at 4 weeks.
- Mean Hb increase ≥ 20 g/L at any time.
- Significant cardiovascular disease, congestive heart failure, or other serious adverse events.

**Statistical analysis**

- All cause: FCM = 119, Venofer = 118.
- Maximum marrow iron increase: FCM = 119, Venofer = 118.

**Study limitations**

- Study design limitations.
- Small sample size.
- Lack of Blinding.

**Conclusion**

- FCM is an effective and safe treatment for postpartum anemia.
- Further research is needed to evaluate the long-term effects of FCM treatment.

---

**Reference**

Open-label, multicenter, randomized, active control, parallel group study.

**Women with androgen deficiency due to heavy uterine bleeding**

- Women aged ≥8 years
- Hb ~ range of two samples below 110 g/L, ferritin ≤100 µg/L, TSAT ≤20%
- Heavy uterine bleeding for 6 months
- Exposure to control
- Parallel group study

**Stratification level of anaemia and severity of uterine blood loss**

- Hypersexuality to hysterectomy
- Blood transfusion or parenteral iron within 6 weeks
- DTO within 6 weeks or during study
- Other types of anaemia or uncontrolled B-12 or folate deficiency
- Fe shortage disorder
- Medication likely to affect iron absorption
- Rental: 0.5 mg three times a day for 5 weeks
- Oral iron = 325 mg tablets

**ITT randomization and one dose of medications**

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<tr>
<th>Treatment</th>
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<th>FCM 33 ± 15 g/L</th>
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**Success defined as increase of Hb from baseline of 20 g/L at any time**

- Change in Hb, ferritin, TSAT
- Combinations of success based on change in Hb, ferritin, and TSAT

**Randomization of 2 women with postpartum anaemia**

- Age - mean 38 years (range 18-64)
- Severity of anaemia - 58%
- Black - 46%
- Hispanic - 22%
- Asian - 22%
- TSAT - mean 50% (range 1-82)

**ITT randomization and one dose of medications**

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**Adverse events**

- Oral iron = 0/226
- FCM = 0/230
- Death
- Effective events
- Oral iron = 1/226
- FCM = 1/230
- Death
- Oral iron = 0/226
- FCM = 0/230
- Death

**Serious adverse events**

- Oral iron = 1/226
- FCM = 1/230
- Death
- Oral iron = 0/226
- FCM = 0/230
- Death

**Ferritin (≥160 µg/L)**

- Oral iron = 16/178
- FCM = 156/174
- Death
- Effective events
- Oral iron = 15/178
- FCM = 151/174
- Death
- Oral iron = 14/178
- FCM = 146/174
- Death

**TSAT (≥50%)**

- Oral iron = 16/178
- FCM = 156/174
- Death
- Effective events
- Oral iron = 15/178
- FCM = 151/174
- Death
- Oral iron = 14/178
- FCM = 146/174
- Death

**Hypersensitivity to iron**

- Oral iron = 16/178
- FCM = 156/174
- Death
- Effective events
- Oral iron = 15/178
- FCM = 151/174
- Death
- Oral iron = 14/178
- FCM = 146/174
- Death

**FGD = 1568 ± 422 mg**

- Oral iron = 6764 ± 1403 mg
- FCM = 1403 ± 211 mg
- Death
- Effective events
- Oral iron = 1516 ± 230 mg
- FCM = 230 ± 456 mg
- Death
- Oral iron = 1469 ± 230 mg
- FCM = 230 ± 456 mg
- Death

**Total dose of iron received:**

- Oral iron = 225 µg/L
- FCM = 211 µg/L

**Hypertension**

- Oral iron = 1/178
- FCM = 1/174
- Death
- Effective events
- Oral iron = 0/178
- FCM = 0/174
- Death
- Oral iron = 0/178
- FCM = 0/174
- Death

**Reticulocytes - mean change to week 6:**

- Oral iron = 44 g/L
- FCM = 44 g/L

**Mean Hb change week 6:**

- Oral iron = 178 g/L
- FCM = 174 g/L

**Six weeks**

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**Serious adverse events**

- Oral iron = 1/226
- FCM = 1/230
- Death
- Effective events
- Oral iron = 0/226
- FCM = 0/230
- Death
- Oral iron = 0/226
- FCM = 0/230
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**TSAT (≥50%)**

- Oral iron = 16/178
- FCM = 156/174
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- Effective events
- Oral iron = 15/178
- FCM = 151/174
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**Gastrointestinal cause of anaemia**

**ITT/IC 020 [56]**

Open, uncontrolled cohort study. Patients with Hb <10 g/L, with stable disease

- **Adverse event or intermittent illness**
  - C1 - 400
  - C2 - 206

- Hypertransamnase in therapies
- Blood transfusion or IV iron within 4 weeks
- Serum ferritin <150 µg/L and serum TIS >45%
- Other types of anaemia or untreated B12 or folate deficiency

Iron storage disorder
Treatment with investigational drug within 4 weeks
Other serious illness

**ITT/IC 026 [57]**

Randomised, open-labelled study. Patients with iron deficiency anaemia (Hb 70-120 g/L in females, 130-160 g/L in males) and with mild to moderate iron deficiency (Hb >110 g/L; mean of two Hb values on different days), TSAT <20%

**Other exclusions were**
- intercurrent illness and serum TfS >45%
- Other types of anaemia

- **Controlled trial with IV iron**
- FCM (1000 mg or 500 mg; IR 300 mg)
- Iron sucrose (120 or 130 g/L)

**ITT/IC 038 [58]**

Cohort 1: 500 mg (last dose lower depending on IV requirement) as IV infusion weekly for up to 4 weeks
Cohort 2: 1000 mg (last dose lower depending on IV requirement) as IV infusion weekly for up to 2 weeks

**Cohort 3**

- **Patients with Hb ≤110 g/L (mean of two Hb values on different days), TSAT <20%**
  - Mean TSAT - 9.3% (range 1-23%)
  - IS = 136/239
  - Mean ferritin change (4 week follow up)
  - C1 - 0/20
  - C2 - 0/20
  - C3 - 22/244

- **Anaemia secondary to chronic disease (Chrohn's disease or ulcerative colitis)**
  - Mean TSAT - 20-50%
  - IS = 8/239
  - Mean ferritin change
  - C1 - 76/20 µg/L
  - C2 - 34/20 µg/L

- **Anaemia secondary to inflammatory bowel disease**
  - Mean TSAT - 23%
  - IS = 4/20
  - Mean ferritin change
  - C1 - 420/20 µg/L
  - C2 - 400/20 µg/L

- **Co - 17/26**
  - Mean TSAT - 78%
  - IS = 120/20 µg/L
  - Mean ferritin change
  - C1 - 60/20 µg/L
  - C2 - 50/20 µg/L

- **Post treatment - 4 weeks after last dose**
  - C1 - 120/20 µg/L
  - C2 - 120/20 µg/L

- **Mean Hb change**
  - C1 - 30/20 g/L (week 4)
  - C2 - 17/20 g/L (week 2)

- **Hypersensitivity to FCM**
  - C1 - 78/20 (week 4)
  - C2 - 57/20 (week 4)

- **Serious AE**
  - C1 - 9/20
  - C2 - 9/20

- **Deaths**
  - C1 - 9/20
  - C2 - 9/20

- **No reports of hypertension**

**Esterhai et al. Gastroenterol 2011. Epis June 12 [49]**

randomised, open, comparison between IV FCM with IV iron sucrose (ferlex) with outcomes measured after 12 weeks, randomisation by computer generated code

- **Adverse event or intermittent illness**
  - C1 - 400
  - C2 - 206

- Hypertransamnase in therapies
- Blood transfusion or IV iron within 4 weeks
- Serum ferritin <150 µg/L, OR TSAT <20%
- Iron requirement at least 1,000 mg

Iron storage disorder
Treatment with investigational drug within 4 weeks
Other serious illness

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Treatment with investigational drug within 4 weeks
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<tr>
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<th>Authors</th>
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<th>Randomisation</th>
<th>Outcome Measures</th>
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<tbody>
<tr>
<td>[1]</td>
<td>Anker et al.</td>
<td>Iron deficiency anaemia of mixed origin</td>
<td>Randomised, double blind, parallel group comparison of IV FCM and IV placebo over 7 days for AE only</td>
<td>Patients with iron deficiency from any cause</td>
<td>Randomisation stratified by condition and centre</td>
<td>Placebo comparison in blind, parallel, placebo group</td>
<td>Mean age about 70 years Women - about 64% Caucasian - 100% Baseline Hb = 100 µg/L Ferritin - range of means 17-77 µg/L TSAT - range of means 16-18% Placebo = 155 FCM = 304 (4 cardiovascular causes) Death = 4/155 Placebo = 2/15</td>
</tr>
<tr>
<td>[2]</td>
<td>CARS 1 [2]</td>
<td>Randomised, double blind, parallel, placebo and active controlled trial</td>
<td>Adults ≥ 18 years None given</td>
<td>Patients with CHF, renal failure, and inflammatory bowel disease</td>
<td>Placebo = 582 randomised and 576 received at least one dose</td>
<td>Double blind = 2 Withdrawals = 1</td>
<td>Mean Hb change by week 12 FCM = 150 ± 12 µg/L Placebo = 132 ± 12 µg/L Mean TSAT change by week 12 FCM = 8.6 ± 5.8% Placebo = 6.3 ± 5.0% Placebo = 13/27 Venofer = 1/27 (cardiac failure) Placebo = 0/27 Venofer = 5/27 Placebo = 0/27</td>
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<td>[3]</td>
<td>Heart failure study</td>
<td>Randomised, multicentre, double blind, parallel group placebo comparison in patients with heart failure</td>
<td>Ambulatory CHF patients NYHA Class II or III LVFS ≥40% (B) or ≥35% (D) Ferritin &gt;100 µg/L or ≤100-300 µg/L when TSAT ≥20% Baseline Hb ≥135 g/L</td>
<td>Anaemia other than iron deficiency Active inclusions AST ≥1.5x ULN History of transfusion, cardiac surgery, or intra coronary intervention in last 3 months</td>
<td>Placebo = 559 of these had both doses</td>
<td>Total = 5/5 FCM = 0/559 Placebo = 12/592 FCM = 14/548</td>
<td>At least 1 adverse event FCM = 1/548 Placebo = 11/548 Death = 1/548 Placebo = 1/548</td>
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