Surgery timeline
Iron needs throughout the surgical journey

Pre-operatively, IV iron should be used as front-line therapy in patients diagnosed with iron deficiency.

Effective management of pre-operative anaemia has post-operative benefits, including reduced hospital LOS, infections and transfusions (and associated risks). *

Hb, haemoglobin; IV, intravenous; LOS, length of stay.

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Iron needs throughout the surgical journey

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Identify and address pre-operative anaemia at least 4 weeks prior to surgery.

Up to 50% (624/1241) of patients scheduled for elective surgery could be anaemic.

Pre-operative anaemia (most frequently caused by iron deficiency) is associated with adverse outcomes.

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Hb, haemoglobin; IV, intravenous; LOS, length of stay.
International consensus statement*
Diagnosing pre-operative anaemia¹

*Pharmacosmos provided logistical support and funding to allow the expert panel to meet. Pharmacosmos had no influence over the content of the publication.

CRP, C-reactive protein; Hb, haemoglobin; TSAT, transferrin saturation.


Women with a pre-operative Hb of 120 g/l are twice as likely to require a transfusion as men with an Hb of 130 g/l; a threshold of 130 g/l is recommended for both sexes¹
Pre-operatively, IV iron should be used as front-line therapy in patients diagnosed with iron deficiency. IV, intravenous; LOS, length of stay.

Investigate anaemia in patients anticipated to lose >500 ml of blood and/or have a ≥10% chance of needing transfusion.

Women with Hb 120 g/l are twice as likely to require a transfusion as men with Hb 130 g/l.
Therefore, Hb ≥130 g/l is a suitable target in both sexes.

Effective management of pre-operative anaemia has post-operative benefits, including reduced hospital LOS, infections and transfusions (and associated risks).

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PREVENTT
A randomised, double-blind, controlled trial

Hypothesis: IV iron given to anaemic patients before major open elective abdominal surgery would correct anaemia, reduce the need for blood transfusions and improve patient outcomes

Patients: 474 patients with anaemia (Hb <130 g/l for men and <120 g/l for women) from 46 UK tertiary care centres scheduled to undergo abdominal surgery

Treatment: Random assignment to a single dose of 1000 mg IV iron or placebo

Outcomes: No significant difference between IV iron and placebo in the co-primary endpoints

- Risk of the composite outcome of blood transfusion or death: 29% (69/237) in the IV iron group and 28% (67/237) in the placebo group (p=0.84)
- Number of blood transfusions from randomisation to 30 days post-operatively: 105 in the IV iron group and 111 in the placebo group (p=0.93)

Analysis:

- Iron status: While the patients fulfilled criteria for anaemia, only a small proportion were iron deficient: 29% (70/244) in the IV iron group and 28% (69/243) in the placebo group
- Dose of iron received: The IV iron dose administered (1000 mg) may be less than surgical patients need: according to real-world service evaluation data from the UK (Royal United Hospital, Bath), 76% of surgical patients had high iron need, receiving a mean dose of 1400 mg

Hb, haemoglobin; IV, intravenous.
Iron needs throughout the surgical journey

Assess all patients after major surgery who had pre-operative anaemia or moderate-to-severe blood loss.

Up to 80–90% *(depending on definition)*

of major surgeries result in post-operative anaemia.*

A single high-dose IV iron infusion is recommended to replenish iron stores post-operatively.

Effective management of pre-operative anaemia has post-operative benefits, including reduced hospital LOS, infections and transfusions (and associated risks).*

*Pre-operatively, IV iron should be used as front-line therapy in patients diagnosed with iron deficiency.*

Hb, haemoglobin; IV, intravenous; LOS, length of stay.
International consensus statement*
Post-operative anaemia

Up to 90% of patients may have anaemia after major surgery

- Uncorrected pre-operative anaemia may contribute to this

Increased hepcidin due to the inflammatory response to surgery can reduce iron absorption for a number of weeks post-operatively, aggravating IDA.

For post-operative iron repletion:

- Early IV iron therapy is recommended, after considering contraindications
- This should be given using a single high-dose preparation where possible

Oral iron is not recommended because of:

- Poor absorption
- Considerable side effects

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IDA, iron-deficiency anaemia; IV, intravenous.
NICE
Rationale for treating iron deficiency anaemia

Pre-operative anaemia is associated with increased post-operative:

- **Morbidity**
- **Mortality**
- **Transfusion need**

Treating iron deficiency with iron supplements can reduce the need for blood transfusions, thus avoiding serious risks such as:

- **Infection**
- **Fluid overload**
- **Incorrect administration of blood transfusions**
- **Allosensitisation and autoimmune challenge to future transplants**

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NICE, National Institute for Health and Care Excellence.


Monofer® (ferric derisomaltose) Prescribing Information

This medicinal product is subject to additional monitoring, and healthcare professionals are asked to report any suspected adverse reaction.

Note: Before prescribing please read full Summary of Product Characteristics.

Pharmaceutical form: Ferric derisomaltose is a dark brown, non-transparent solution for injection/infusion. Presentations: Iron in the form of ferric derisomaltose; 100 mg/ml available in vials of 100 mg/ml, 500 mg/5 ml and 1,000 mg/10 ml. Indications: Monofer® is indicated in patients ≥18 years for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used or when there is a need to deliver iron rapidly. The diagnosis must be based on laboratory tests. Administration: Each IV iron administration is associated with a risk of a hypersensitivity reaction. Thus, to minimise risk, the number of single IV iron administrations should be kept to a minimum. The iron need can be determined using either the Simplified Table, or the Ganzoni formula, or a fixed dose of 1,000 mg can be given to patients ≥50 kg body weight followed by re-evaluation for further iron need, please consult full Summary of Product Characteristics. Monofer® may be administered as an IV bolus injection of up to 500 mg at an administration rate of up to 250 mg iron/minute up to three times a week, during a haemodialysis session directly into the venous limb of the dialyser under the same procedures as outlined for IV bolus injection, or as an up to 20 mg iron per kg body weight infusion. If the iron need exceeds 20 mg iron per kg body weight, the dose must be split into two administrations with an interval of at least one week. It is recommended whenever possible to give 20 mg iron/kg body weight in the first administration. Dependent on clinical judgement the second administration could await follow-up laboratory tests. Doses up to 1,000 mg must be administered over >15 minutes; doses above 1,000 mg must be administered over ≥30 minutes. In case of infusion, Monofer® should be infused undiluted or diluted in 0.9% sodium chloride. For stability, Monofer® should not be diluted to concentrations less than 1 mg iron/ml and never diluted in more than 500 ml. Contraindications: Non-iron deficiency anaemia, iron overload or disturbances in utilisation of iron, hypersensitivity to any of the ingredients, decompensated liver disease, or known serious hypersensitivity to other parenteral iron products. Warnings/Precautions: Parenterally administered iron preparations can cause hypersensitivity reactions including potentially fatal anaphylactic/anaphylactoid reactions. The risk is enhanced for patients with known allergies, a history of severe asthma, eczema or other atopic allergy, and in patients with immune or inflammatory conditions. Monofer® should only be administered in the presence of staff trained to manage anaphylactic reactions where full resuscitation facilities are available (including 1:1000 adrenaline solution). Each patient should be observed for at least 30 minutes following administration. If hypersensitivity reactions or signs of intolerance occur during administration, the treatment must be stopped immediately. In patients with compensated liver dysfunction, parenteral iron should only be administered after careful benefit/risk assessment. Careful monitoring of iron status is recommended to avoid iron overload. Parenteral iron should be used with caution in case of acute or chronic infection. Monofer® should not be used in patients with ongoing bacteraemia. Hypotensive episodes may occur if intravenous injection is administered too rapidly. Caution should be exercised to avoid paravenous leakage when administering Monofer®. Pregnancy: Monofer® should not be used during pregnancy unless clearly necessary. The treatment should be confined to second and third trimester. In rare cases, foetal bradycardia has been observed in pregnant women with hypersensitivity reactions. The unborn baby should be carefully monitored during intravenous administration of parenteral iron in pregnant women. Undesirable effects: No very common (≥10 %) undesirable effects listed. Common undesirable effects (1 % to 10 %): nausea; rash; injection site reactions. For information on other undesirable effects, please consult full Summary of Product Characteristics. Legal Category: POM. Package Quantities and basic Prices: 5 vials of 1 ml, £84.75; 5 vials of 5 ml, £423.75; 2 vials of 10 ml, £339.00. Marketing Authorisation Number/Holder: PL 18380/001, Pharmacosmos A/S, Roervangsvej 30, DK-4300 Holbaek, Denmark. Date of preparation: August 2020. Further information is available on request to Pharmacosmos UK.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Pharmacosmos UK Ltd.

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