CLINICAL PROTOCOL FOR IRON CARBOXYMALTOSE INFUSION

SCOPE: Western Australia

Inclusion Criteria	Exclusion Criteria
There are four required inclusion criteria: Meet criteria for iron depletion/iron deficient erythropoiesis/IDA as defined below **AND** Demonstrated intolerance, non-compliance or lack of efficacy with oral iron, despite modification of dose, timing and frequency • The patient's medical condition has been assessed as stable; • The patient has a clear diagnosis and prognosis and is at a low risk of deterioration; and • The referrer has discussed the risks and benefits of intravenous iron treatment.	• Previous hypersensitivity reaction to any intravenous iron. • Anaemia not caused by iron deficiency. • Haemachromatosis. • Pregnancy.

SPECTRUM OF IRON DEFICIENCY

Example of laboratory profile	Normal	Iron depletion	Iron deficient erythropoiesis	Iron deficiency anaemia
Serum ferritin (µg/L)	60	<15	<15	<15
Transferrin saturation (%)	35	35	<15	<15
Haemoglobin (g/L) female	>120	>120	>120	<120
Haemoglobin (g/L) male	>130	>130	>130	<130

NOTE

- All referrals should be provisionally accepted upon confirmation that the pathology requirement is available and the referrer should be informed that the governing doctor will assess the pathology results and clinical information and will make contact should any further information be required prior.
- Please check if there is a history of drug hypersensitivity, asthma, or other co-morbidities. While they may still be considered to be suitable for iron infusions the information is required for the governing doctor to make an assessment.
- Please advise the referrer to cease oral iron in order to allow at least 1 week of no oral iron prior to the infusion as the presence of oral iron may reduce the effectiveness of the infusion.

PATHOLOGY REQUIRED

U&E, FBP, Full iron studies.

PRACTICE POINTS

- Deficiency of iron may lead to fatigue, shortness of breath, decreased physical performance, impaired learning in children and adults, altered body temperature, and altered immune function. The cause of iron deficiency states should always be determined, as it may relate to a serious condition

- Anaphylactoid reactions occur most frequently within the first several minutes of administration and are characterised by sudden onset of respiratory difficulties, tachycardia and hypotension. Adrenaline and facilities for the cardio-pulmonary resuscitation must be available. Therefore, the infusions of iron carboxymaltose will only be completed in a clinic environment.

- **Extravasation:** Both patient and nurse must be alert to extravasation at all time. Skin staining as a result of extravasation is irreversible. Ensure cannula is in the largest vein possible and secured and an extension is used. Flush with 50mls Normal saline 0.9% prior to and following infusion to minimise risk.

- **Drug interactions**: Oral iron therapy – if possible cease one week prior to and at least one week after infusion. Oral and parenteral iron should not be used together. Oral iron may block iron binding sites so that intravenous iron is less well absorbed and there is a greater likelihood of adverse effects.

- Absolute iron deficiency is defined as Ferritin <15-30 microgram/L or Ferritin <100 microgram/L and Transferrin saturation <20%. Functional iron deficiency exists, when stored iron cannot be released for erythropoiesis. This is commonly seen in patients with kidney disease, inflammatory states or cancer.

DOSAGE

- Iron Carboxymaltose (Ferinject®)
- Classification: Iron supplementation
- Presentation: Ferric carboxymaltose.
- 500mg elemental iron /10mL (Ferinject®)

There are two components to the dosage calculation. The first is the total dose to be given and this is calculated based on weight and haemoglobin. Since more than one infusion may be required, the second is the dose to be given on each occasion.

Total Dosage Calculation Based on Weight and Haemoglobin

Total Ferric carboxymaltose dose required based on haemoglobin and body weight Haemoglobin (g/L)	Body Weight 35kg - <70 kg	Body Weight ≥ 70kg
< 100	**1500mg**	**2000mg**
≥ 100	**1000mg**	**1500mg**

Maximum Dose

The maximum dose is 1000mg (not exceeding 20mg/kg) in a week. (Maximum PBS quantity is 2 vials per prescription)

Dose per Infusion

The following doses are suggested per infusion based on body weight:

- ≤55kg – 500mg elemental iron (as ferric carboxymaltose)
- >55kg – 1000mg elemental iron (as ferric carboxymaltose)

ADMINISTRATION

Preparation

Ensure resuscitation equipment is readily available (including oxygen, adrenaline, hydrocortisone and promethazine).

Dilute:
- 500mg ferric carboxymaltose in 100mL sodium chloride 0.9%.
- 1000mg ferric carboxymaltose in 250mL sodium chloride 0.9%.

Infusion

Secure IV access should be established, bearing in mind when selecting the site that there could be irreversible staining with extravasation.

Flush with 50mL sodium chloride 0.9% before and after iron infusion to minimise risk of extravasation.

Infuse over 15 minutes. No test dose required.

Observations

Temperature, pulse, respiratory rate, blood pressure and oxygen saturation prior to commencement of the infusion (baseline), 5 minutes into the infusion, if the patient reports feeling unwell/any potential adverse effects, and at the end of the infusion.

Patients must be observed for 30 mins following the infusion.

Adverse Effects

- Phlebitis
- Flushing, sweating, chills, fever, headache, dizziness
- Nausea and vomiting
- Rash, urticaria, angioedema
- Anaphylaxis
- Syncope, tachycardia, hypotension,
- Bronchospasm, dyspnoea
- Musculoskeletal pain/stiffness
- Adverse reactions may be delayed by 1-2 days following infusion

Contraindications

Absolute

- Allergy to ferric carboxymaltose or excipients
- 1st trimester of pregnancy
- Iron overload
- Anaemia not attributed to iron deficiency

Relative

- Acute or chronic infection
- Asthma, eczema or atopic allergies
- Hepatic dysfunction

Following Infusion(s)

One or more infusions will be arranged as required using the calculations above.

If more than one infusion is required, arrange the next infusion at least 7 days later, and inform the patient's GP after each time that the infusion has occurred and when the next infusion will occur patient.

Following the last infusion, the patient's GP should be advised to recheck iron level between 21 and 28 days following the final infusion to ensure iron levels have improved.

Recurrent need for infusion should be investigated. The risks of iron toxicity are increased with recurrent infusions.

REFERENCES

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6. Government of South Australia SA Health. Ferric Carboxymaltose (Ferinject®) Infusion for ADULTS with confirmed iron deficiency and indications for IV iron. Version 1.0. 2017; http://www.sahealth.sa.gov.au/wps/wcm/connect/56c9728042c5cd328b00ff8cd21c605e/Generic+ferric+carboxymaltose+infusion+protocol+for+adults.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-56c9728042c5cd328b00ff8cd21c605e-lX5RWSG
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