University Hospitals of Derby and Burton NHS Foundation Trust

Ferric Carboxymaltose (Ferinject®) for Medical Day Case - Full Clinical Guideline

Reference No: CG-Pharm/2023/002

Aim and Purpose

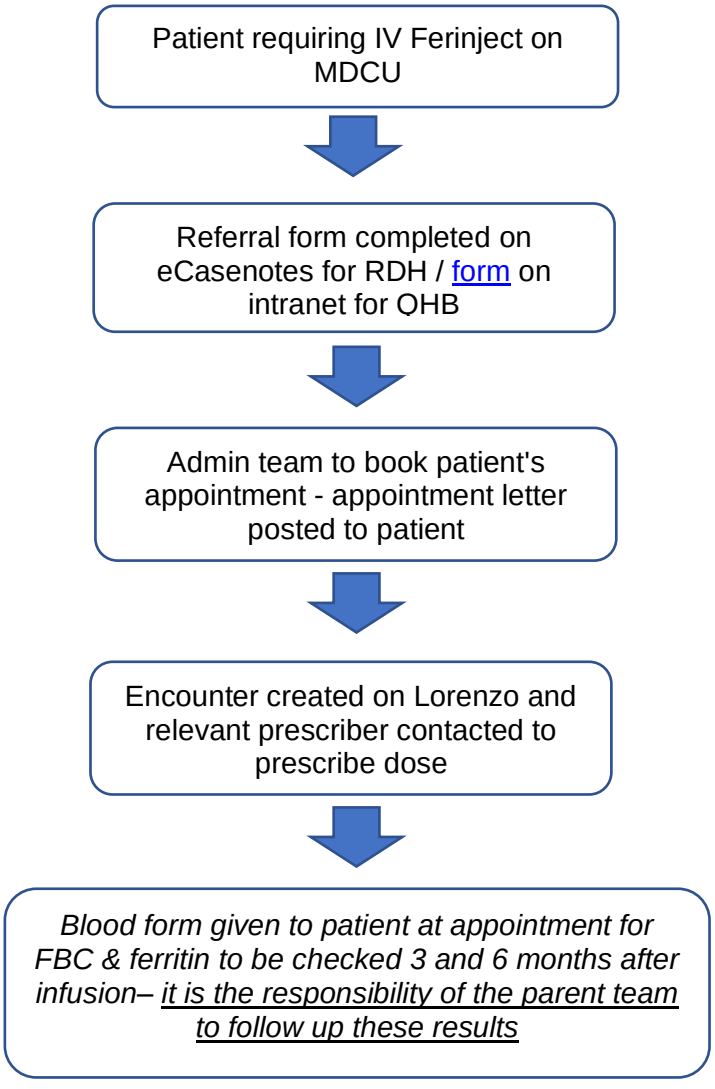
To ensure IV Ferinject® is given consistently and correctly.

Scope

This guideline is specifically for **total dose IV iron infusions for use in adult patients attending the medical day case unit (MDCU)** with iron deficiency anaemia. This guideline does not apply to pregnant women, dialysis patients or inpatients.

Please see separate guidelines available on the Koha.

IV Ferinject® flowchart



Reference ranges

Minimum haemoglobin and haematocrit levels**:**

Sex	Haemoglobin (g/L)	Haematocrit %
Non pregnant women	120	36
Men	130	39

Ferritin**:** normal reference range 15-150μg/L. Ferritin levels can be falsely elevated in patients with inflammatory disease (such as ulcerative colitis or Crohn's disease). Please refer to gastroenterology for advice.

Treatment

IV iron therapy is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.

Ferric Carboxymaltose (Ferinject®) is the preparation of choice for total dose iron infusion on medical day case due to short infusion time.

To calculate the dose of Ferinject® required, the following information is needed.

- Patient's weight.
- Haemoglobin

Full blood count and iron studies should ideally be performed no more than four weeks prior to patient attending the MDCU.

Determining the Iron Dose

Using the table below, calculate the cumulative iron dose to determine the client's TOTAL iron requirement**.**

Cumulative iron doses >1000mg must be split into TWO DOSES given AT LEAST ONE WEEK APART.

The following table should be used to determine the cumulative iron dose:

Hb	**Patient Weight**		
(g/L)	**below 35 kg**	**35 kg to <70 kg**	**70 kg and over**
<100	500 mg	1,500 mg	2,000 mg
100 to <140	500 mg	1,000 mg	1,500 mg
>140	500 mg	500 mg	500 mg

Note:

- A single ferinject administration should not exceed **20mg/kg** body weight for IV infusion
- A cumulative iron dose of 500mg should not be exceeded for patients with a body weight <35kg.

Do NOT administer more than 1000mg of iron in one week.

Dilution and Rate of Infusion

Ferinject® must be diluted in sterile sodium chloride 0.9% solution only. The line should only be flushed with sodium chloride 0.9%. Each 500mg vial of Ferinject® can be reconstituted with a 100ml sodium chloride 0.9% ecoflac. A dose of 500mg or 1000mg should be infused over a minimum period of 15 minutes.

Infusion fluid volume

Dose of Ferinject	**Volume of sodium chloride 0.9%**
500mg	100 mL Ecoflac
1000mg	250 mL Ecoflac

Monitoring

- Check blood pressure (BP) and pulse prior to the start of the infusion.
- Patients should be closely monitored for signs of hypersensitivity during and for at least 30 minutes after every administration of an IV iron product
- Hypersensitivity reactions can be delayed with total dose iron infusions. Respiratory difficulty and/or cardiovascular collapse and fatalities have been reported, and so infusions should only be administered when staff trained to evaluate hypersensitivity reactions as well as resuscitation facilities are immediately available. If there are any signs of hypersensitivity (e.g. urticaria, rashes, itching, nausea and shivering) or intolerance at any stage of the infusion, administration must be stopped immediately.

PARAVENOUS LEAKAGE

Caution should be exercised to avoid paravenous leakage when administering Ferinject. This may lead to irritation of the skin and long-lasting brown discolouration at the site of injection. If paravenous leakage does occur, the administration of Ferinject must be stopped immediately. Withdraw any remaining ferinject from cannula. Escalate to medical, senior nurse and pharmacy if required.

- Ferric carboxymaltose (Ferinject) is known to be commonly associated with hypophosphatemia. Cases have been reported of symptomatic hypophosphataemia leading to infrequent reports of hypophosphataemic osteomalacia and fractures in patients with existing risk factors and following prolonged exposure to high doses – some cases required clinical intervention, including surgery.
    - Monitor serum phosphate levels in patients:
        - requiring multiple administrations of ferric carboxymaltose at higher doses
        - on long-term treatment with ferric carboxymaltose
        - with pre-existing risk factors for hypophosphataemia such as vitamin D deficiency, calcium and phosphate malabsorption, secondary hyperparathyroidism, inflammatory bowel disease, and osteoporosis
    - Advise patients to seek medical advice if they experience symptoms indicative of hypophosphataemia, including new musculoskeletal symptoms or worsening of tiredness – be aware these symptoms may be confused with those of iron deficiency anaemia
    - If hypophosphataemia persists, re-evaluate treatment with ferric carboxymaltose
    - Report all suspected adverse drug reactions to ferric carboxymaltose to the Yellow Card scheme without delay.

Further prescribing information

Cautions when using Ferinject®

- Allergic disorders including asthma and eczema or other atopic allergies.
- Immune or inflammatory conditions (e.g. systemic lupus erythematosus, rheumatoid arthritis) as increased risk of hypersensitivity reactions
- Acute or chronic infection infection (discontinue if ongoing bacteraemia)
- Hepatic dysfunction (avoid if risk of iron overload)
- Hypertension and other conditions requiring sodium-controlled diet (due to sodium content of Ferinject® vials). One mL of undiluted Ferinject contains up to 5.5 mg (0.24mmol) of sodium.
- Oral iron should not be given until after 5 days of the last Ferinject® injection (due to the reduced absorption of oral iron when administered concomitantly)

Contraindications to using Ferinject®:

- Hypersensitivity to the active substance (Ferinject) or any of its excipients
- Known serious hypersensitivity to other parenteral iron products
- Anaemia not attributed to iron deficiency e.g. other microcytic anaemia
- Evidence of iron overload or disturbances in the utilisation of iron
- First trimester of pregnancy

Follow up post infusion

Once normal, the Hb concentration and red cell indices should be monitored at intervals.
A suitable suggestion would be 3 monthly for 1 year, then after a further year, and again if symptoms of anaemia develop after that.

References

Joint Formulary Committee. *British National Formulary* (online) London: BMJ Group and Pharmaceutical Press. Available from: https://www.medicinescomplete.com/mc/bnf/current/PHP5859-ferinject.htm?q=ferinject&t=search&ss=text&p=1#PHP5859-ferinject

Electronic Medicines Compendium. *Ferinject (Ferric Carboxymaltose) SPC* (online) EMC. Available from: https://www.medicines.org.uk/emc/product/5910/smpc

British Society of Gastroenterology Guidelines for the Management of Fe Deficiency Anaemia (Goddard et al; Gut 2011; 60:1309 - 1316).

Documentation Controls

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