Worcestershire Acute Hospitals NHS Trust

GUIDELINE FOR ADMINISTRATION OF FERINJECT INFUSION FOR MANAGEMENT OF IRON DEFICIENCY ANAEMIA (IDA)

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Approved by:	Maternity Governance Meeting	
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Key Amendments

Date	Amendments	Approved by

INTRODUCTION

Ferinject is ferric carboxymaltose used to treat iron deficiency anaemia (IDA).This guideline covers the use of Ferinject in pregnant and post-partum women. Ferinject is for use in adults only. Other indications outside pregnancy are not included in this guideline. The indications, contra-indications and dosage schedule are covered in detail in this guideline.
Ferinject infusion replaces Cosmofer infusion for management of iron deficiency anaemia in pregnancy. This guideline replaces Cosmofer guideline WAHT-OBS-107.

THIS GUIDELINE IS FOR USE BY THE FOLLOWING STAFF GROUPS :

Midwives, Obstetricians and Pharmacists.

The incidence of anaemia in pregnancy is estimated at 25% globally[1]. Even in the developed world Iron deficiency affects 30- 40% of preschool children and pregnant women (WHO, 2008). Anaemia is defined by Hb <110g/l in first trimester, <105g/l in second and third trimesters and <100g/l in postpartum period. The other indices that confirm iron deficiency anaemia are MCH<27pg and low ferritin (<12ng/ml). Some patients may have iron deficiency without anaemia.
Iron deficiency can lead to increased risk of maternal infection through the effects on immune system. There is recognised association between maternal iron deficiency and preterm delivery and low birth weight. There is evidence that anaemia in the mother can increase the risk of iron deficiency in the first 3 months of life in new-born.
Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron. While oral iron administration is satisfactory for many patients with IDA intolerance, malabsorption or poor compliance are frequent concerns. Ferinject infusion can be used to correct IDA (iron deficiency anaemia) in the second or third trimesters of pregnancy.
There are no adequate and well-controlled trials of Ferinject in pregnant women. A careful benefit/risk evaluation is required before use during pregnancy and Ferinject should not be used during pregnancy unless clearly indicated. Animal studies have shown association with abnormal skeletal development and Ferinject use in pregnancy.
The Summary of Product Characteristics for Ferinject states that treatment with Ferinject should be confined to the second and third trimester if the benefit is judged to outweigh the potential risk for both the mother and the fetus.

INDICATIONS

Treatment of IDA in pregnancy:

Ferinject is indicated for the treatment of iron deficiency in the following circumstances:

- Hb <105g/l in 2nd and 3rd trimesters
- Demonstrated intolerance to oral iron preparations.

- Where there is a clinical need to deliver iron rapidly to iron stores.
- Demonstrated lack of effect of oral iron therapy.

Treatment of IDA in post-partum women:

- Postpartum Hb <100g/l
- Ferinject can be secreted in the breast milk in ≤1%.
- Based on limited data Ferinject is unlikely to represents a risk to the nursing child.

Prophylactic Treatment in pregnancy:

- Use Prophylactic treatment with normal Hb range from 110-140g/l
- Ferinject infusion should be considered prophylactically in:
    - Multiple pregnancy, Grand-multiparity, Placenta Previa- High PPH risk
    - Jehovah's Witness

DRUG INTERACTION

- Ferinject injection should not be administered concomitantly with oral iron preparations as the absorption of oral iron will be reduced.
- Oral iron therapy should not be started earlier than 5 days after the last injection of Ferinject.

CONTRAINDICATIONS

- Non-iron deficiency anaemia (e.g. haemolytic anaemia). .
- Drug hypersensitivity to the active substance, to Ferinject or any of its excipients such as Sodium hydroxide and Hydrochloric acid.
- Known serious hypersensitivity to other parenteral iron products.
- Immune or inflammatory conditions such as systemic lupus erythematosus, rheumatoid arthritis where there is an increased risk of hypersensitivity reactions to parenteral iron complexes.
- Iron overload or disturbances in utilisation of iron (e.g. haemochromatosis, haemosiderosis, decompensated liver cirrhosis, hepatitis and in particular Porphyria Cutanea Tarda).
- Parenteral iron must be used with caution in case of acute or chronic infection, asthma, eczema or atopic allergies

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Ferinject can cause serious anaphylaxis or anaphylactoid reactions. Hypersensitivity reactions are known to have occurred with previous uneventful parenteral infusion of iron.
- Ferinject should be administered in a place where there is availability for immediate resuscitation. Equipment for resuscitation and drugs to treat serious anaphylaxis should be available including adrenaline, antihistamines and/or corticosteroids.
- Staff should stop the Ferinject infusion if hypersensitivity reaction is noted and seek medical review
- Paravenous leakage of Ferinject at the injection site may lead to irritation of the skin and potentially long lasting brown discolouration at the site of injection. In case of paravenous leakage, the administration of Ferinject must be stopped immediately.
- A single dose of Ferinject should not exceed 1000mg of iron as an infusion. The cumulative dose of Ferinject in one week should not exceed 1000mg.

ADVERSE DRUG REACTION

- The most commonly reported adverse drug reaction is nausea (occurring in 3.1% of the patients), followed by headache, dizziness, and hypertension.
- The other uncommon reactions include Hypersensitivity, Paraesthesia, dysgeusia, Tachycardia, Hypotension, flushing, Dyspnoea, vomiting, dyspepsia, abdominal pain,

constipation, diahorrea pruritus, urticaria, erythema, rash, myalgia, back pain, arthralgia, muscle spasms, pyrexia, fatigue, chest pain and chills
- The rare reactions include Anaphylactoid reactions, bronchospasm and syncope.

CONSENT

- Explain the indication for Ferinject infusion, the potential risks and explain the procedure to the patient and gain informed verbal consent.

PLACE OF ADMINISTRATION OF FERINJECT INFUSION:

- It is agreed that women across the three sites (Worcester, Kidderminster and Redditch) will have the infusion in Medical Day Case , Worcester Royal Hospital.
- See appendix 1 for a pathway to arrange the infusion.

DOSE CALCULATION

- The cumulative dose for repletion of iron using Ferinject is determined based on the patient's body weight at booking and haemoglobin (Hb) level. This should prescribed on prescription sheet.
- If the BMI is more than 30 then ideal body weight should be used to calculate the dose. Use the formula given below to calculate the ideal body weight.

IBW (Female) = (2.3 x height above 152.4cm / 2.54)) + 45
If patient is less than 152.4cm, then use 45kg as IBW or
Use Trust Intranet page- Clinical systems: Ideal Body Weight Calculator tool

- **Determination of the cumulative iron dose:**

Hb (g/L)	**Patients with body weight 35 - 70 kg**	**Patients with body weight ≥70 kg**
The maximum dose given at one time should not exceed 20mg/kg		
<100	1000mg day 1 500mg day8	1000 mg day 1 1000mg day8
≥100	1000 mg day 1	1000 mg day 1 500mg day8

- Booking weight <35 kg: Cumulative iron dose of 500 mg should not be exceeded.
- Booking weight >35kg but <50kg: The maximum dose given at one time must be up to a 20 mg/kg body weight.
- A single dose of Ferinject should not exceed 1,000 mg of iron (20 mL) per day.
- Do not administer 1,000 mg of iron (20 mL) more than once a week.

METHOD OF ADMINISTRATION

- Dilution plan of Ferinject for intravenous infusion:

Ferinject	**Iron**	**Amount of sodium chloride 0.9%**	**Minimum administration time**
2mL-4mL	100mg to 200mg	50mL	2 minutes
>4mL-10 mL	>200mg to 500 mg	100 mL	6 minutes
>10mL -20	>500mg to	250 mL	15 minutes

mL	1,000 mg		

- Ferinject must only be administered only by the intravenous route and given using an infusion pump.
- Intravenous infusion- maximum single dose -1,000 mg of iron (up to 20 mg/kg body weight).
- Sterile 0.9% sodium chloride solution should be used to for the preparation
- One mL of solution contains 50 mg of iron as ferric carboxymaltose.; Each 2 mL vial contains 100 mg of iron as ferric carboxymaltose. Each 10 mL vial contains 500 mg of iron as ferric carboxymaltose. Each 20 ml vial contains 1,000 mg of iron as ferric carboxymaltose.
- Do not dilute to concentrations less than 2mg of iron per mL.

MONITORING OF WOMEN RECEIVING TOTAL DOSE FERINJECT INFUSION

- Record observations: BP, pulse and temperature and Oxygen Saturation at the beginning and end of the 15 minute infusion
- Observe the patient for one hour following the infusion.

CHECKING THERAPEUTIC RESPONSE

- The patient's Hb and ferritin should be measured 4 weeks after the last Ferinject infusion, to confirm the predicted response.

Appendix 1

Pathway to book Ferinject Infusion for pregnant women from Antenatal Clinic

Pregnant women needing Parenteral Ferinject Infusion from Redditch/Kidderminster and Worcester ANC

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Contact WRH extension 30783/30597- Medical Day Case to book the slot for Ferinject administration

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Calculate the dose of Ferinject according to her booking weight
If the total dose required is > 1000mg, it should be given in two divided doses a week apart. See guideline

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Prescribe the dose in a drug chart and send the notes and chart to Avon Discharge Lounge

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Repeat FBC 4 weeks later to assess treatment response

Bleep number for Medical Review:
Obstetric on call SHO - 675
Obstetric On call Registrar- 800
Consultant Obstetrician- 217