Worcestershire Acute Hospitals NHS Trust

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

Key Document code:	WAHT-TP- 094	
Key Documents Owner/Lead:	Dr Hegazy, Miss Veal	Registrar O&G, Consultant O&G
Approved by:	Maternity Governance Meeting/ Medicines Safety Committee	
Date of Approval:	15th July 2022	
Date of review:	15th November 2025	

Key Amendments

Date	Amendments	Approved by
July 2022	Location of Ferrinjet administration changed from the Medical Day Case unit to the Maternity Day Assessment Unit Need for a CTG during administration Appendix 2: Resuscitation Council Management of Anaphylaxis guideline	Obstetric Governance

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 (Iron Deficiency Anaeamia) intolerance, malabsorption or poor compliance are frequent concerns. Ferinject infusion can be used to correct IDA 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, diarrhoea, 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 Maternity Day Assessment Unit, Worcester Royal Hospital.
- The Ferinject ampoules are to be found in the ANC in the locked cupboard in the clean utility room.
- 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 an IV infusion 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 to be given at any one time must not exceed 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 mL	>500mg to 1,000 mg	250 mL	15 minutes

- 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
- 1 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 .
- Listen and record the Fetal heart rate with sonicaid for 1 minute and proceed to administration of Ferinject if normal.
- The pregnant woman should be traced by CEFM throughout administration of Ferinject and not for less than a total of twenty minutes.
- Observe the patient for 30 minutes 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 30124 - Maternity Day Assessment Unit 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

↓

Prescribe the dose on an IV infusion sheet and send over to the DAU/Give the patient their paperwork to take with them on the day

↓

Listen and record the Fetal Heart for 1 minute with sonicaid and proceed to administration if normal

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CEFM for the pregnant woman to be done throughout administration of ferrinjet and for at least twenty minutes in total.

↓

In case of a reaction or an emergency, the nearest resus trolley is to be found on delivery suite and in the case of a second emergency a resus trolley is located on larkspur clinic (Oxygen is available in the antenatal clinic)

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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

Appendix 2: Management of Anaphylaxis

Please refer to Resuscitation council guidelines on anaphylaxis.

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

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Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	**Laura Veal**

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Laura Veal	**Consultant O&G**	**lveal@nhs.net**
Date assessment completed	**15/7/2022**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Administration of Ferinject				
What is the aim, purpose and/or intended outcomes of this Activity?	Location of administration on Ferinject has been changed to Maternity DAU rather than Medical Day Case unit due to needing a CTG during it's administration.				
Who will be affected by the development & implementation of this activity?	❑ X ❑ ❑	Service User Patient Carers Visitors	x ❑ ❑ ❑	Staff Communities Other _____	
Is this:	x Review of an existing activity ❑ New activity				

	❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	BNF recommendations
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Passed through MSC Discussed with staff on Medical Day Case and DAU
Summary of relevant findings	Change in location of administration of Ferinject

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	**Potential positive impact**	**Potential neutral impact**	**Potential negative impact**	**Please explain your reasons for any potential positive, neutral or negative impact identified**
Age		x		
Disability		x		
Gender Reassignment		x		
Marriage & Civil Partnerships		x		
Pregnancy & Maternity	x			Will enable women to have a CTG at the same time
Race including Traveling Communities		x		
Religion & Belief		x		
Sex		x		
Sexual Orientation		x		
Other Vulnerable and		x		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic Nodeprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		X		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	N/A	.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	**Liaise with staff in DAU in 3 months time to assess how they are getting on with things.**			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Laura Veal
Date signed	15/7/2022
Comments:	
Signature of person the Leader Person for this activity	Laura Veal
Date signed	15/7/2022
Comments:	