

FERRIC (IRON) CARBOXYMALTOSE BY INFUSION (FERINJECT®)

This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual woman circumstances may mean that practice diverges from this LOP.

1. AIM

- To replenish iron stores in a woman where oral replacement is not adequate or tolerated
- To reduce need for blood transfusion

2. PATIENT

- Woman with iron deficiency anaemia unresponsive or intolerant to oral iron supplementation
- Woman who is symptomatic or high risk where iron deficiency is diagnosed by a low ferritin (<15ug/L) and/or low transferrin saturation (<15%), with or without a reduction in haemoglobin (Hb <100 g/L)
- Woman who is unwilling/unable to accept blood products
- Woman at risk of excessive intrapartum/intraoperative blood loss

3. STAFF

- Medical, nursing and midwifery staff
- Pharmacist

4. EQUIPMENT

- Resuscitation equipment
- 20 gauge or smaller cannula
- Intravenous (IV) starter kit
- Infusion pump
- Infusion set
- Cardiotocograph (CTG)/hand held Doppler
- Hospital Ferinject® stamp

5. CLINICAL PRACTICE

- Identify woman requiring iron infusion who meets the above criteria
- Provide woman with the information leaflet (Appendix 1)
- Discuss the procedure with the woman including potential adverse reactions
- Discuss Ferinject® checklist with woman
- Complete documentation and Ferinject® infusion checklist and ensure woman knows to bring it with her on the day of infusion
- Provide prescription for Ferinject®. Outpatient woman is to fill the prescription at a community pharmacy. RHW pharmacy will only provide Ferinject® for inpatient orders
- Book only one infusion per day (for antenatal outpatient) in:
 - Pregnancy Day Stay Unit for public antenatal woman (phone 02 93826417)
 - Antenatal Ward for private antenatal woman (phone 02 93826448)
- Book woman under the care of Midwifery Group Practice (MGP) through the practice. It is the responsibility of the MGP midwife to locate an appropriate venue for administration
- Gain verbal consent for procedure and document in the integrated clinical notes
- Confirm woman's pre-pregnancy weight, or current weight if not pregnant, and document weight on fluid order chart
- Prescribe Ferinject® 500-1000mg on fluid order chart. 1000mg is the standard dose. 500mg may be used in certain circumstances at the discretion of the prescriber
- Do not exceed 1000 mg (20 mL) per day for single dose of Ferinject®. Do not administer 1000 mg (20 mL) more than once a week. The total required dose may be administered in a series of weekly infusions (200-1000mg) over 3-4 weeks.

CLINICAL POLICIES, PROCEDURES & GUIDELINES

Approved by Quality & Patient Care Committee
20 April 2017

FERRIC (IRON) CARBOXYMALTOSE BY INFUSION (FERINJECT®) cont'd

Infusion preparation and administration

- Perform baseline observations including temperature, pulse, blood pressure, respirations and oxygen saturation
- Perform fetal monitoring for antenatal woman. Intermittent auscultation is adequate
- Prepare infusion as per dilution plan:

Dilution and administration plan for Ferinject® (ferric carboxymaltose) for intravenous infusion

Iron dose (ferric carboxymaltose)	Maximum volume of sterile sodium chloride 0.9% solution	Minimum administration time
100–200mg	50 mL	3 minutes
500mg	100 mL	6 minutes
501–1000mg	250 mL	30 minutes

- Do not dilute to concentrations less than 2 mg iron/mL for stability reasons
- Administer intravenously. **Do not** administer by the subcutaneous or intramuscular route
- Insert an IV cannula. Antecubital fossa may be used but it increases the risk of cannula displacement
- Flush the IV cannula with 10mLs normal saline. If there is any pressure, stop immediately. If any concerns re-site cannula
- Immobilise arm and instruct woman to avoid movement of arm to help prevent extravasation.
- Commence IV infusion via pump
- Recommend running infusion over 30 minutes to reduce stinging sensation for the woman
- Remain with the woman at the commencement of the infusion, and for at least the first 5 minutes to observe for any adverse reactions. Attend a second set of observations at 5 minutes and continue to observe the woman to identify any adverse reaction. If adverse reaction occurs, turn off infusion and request medical review immediately. Initiate PACE or Code Blue if criteria met.
- Be particularly aware of signs and symptoms of infiltration/extravasation. (Appendix 2)
- Flush the IV cannula with 10mLs normal saline on completion of infusion and remove cannula
- Perform final set of observations, including fetal monitoring for antenatal woman. Intermittent auscultation is adequate
- Continue to observe woman for adverse effects for at least 30 minutes following completion of infusion
- Complete documentation in the integrated clinical notes. For antenatal woman, use Ferinject® stamp on antenatal card and antenatal short stay observation chart

Treatment for anaphylactic reaction

- Turn off infusion
- Initiate PACE or CODE BLUE call and commence resuscitation
- Give promethazine, hydrocortisone and paracetamol for mild reactions, as ordered by medical officer
- Complete IIMS and forward to pharmacy who will complete Adverse Drug Reaction (ADR) form

Follow Up

- Advise woman not to take oral iron supplementation for at least 5 days post infusion. Recommencement of oral iron supplementation is not usually required but management should be individualised (See educational notes)
- Book subsequent infusions for woman who requires more than one infusion of Ferinject®
- Check Hb and iron studies/ferritin after 4-6 weeks depending on clinical scenario

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6. DOCUMENTATION

- Integrated Clinical Notes
- Standard Maternity Observation Chart
- Adult fluid order chart
- Antenatal Card
- Antenatal Short Stay observation chart

7. EDUCATIONAL NOTES

- All staff involved with this procedure must be aware of and able to manage adverse reactions.
- Outpatient infusions are to be administered in business hours, before 4pm.
- Infusion must always be administered with ready access to resuscitation equipment.
- Caution must be taken where there is suspected acute or chronic infection as iron is essential for bacterial growth.
- Infusion may be given over 15 minutes however RHW recommends 30 minutes to reduce stinging sensation for the woman.
- In the case of infiltration/extravasation leading to skin staining, laser therapy has been successful in reducing skin staining long term.
- Following Ferinject infusion, changes to iron level/stores should be noticeable after 2 weeks. The full effects should stabilise after about 4 weeks (which is why the product information mentions review after 4-6 weeks).
- Oral iron supplements should NOT be used in the first 5 days following Ferinject infusion, as the oral supplements will not be absorbed during this period.
- Continuing oral supplementation post infusion ultimately depends on the woman's situation and the clinical judgement of the prescriber. Oral supplementation is not usually required to maintain adequate iron levels, once infusion has been given.

8. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP

- Blood Component Management and Administration Clinical Business Rule POWH
- Anaemia and Haemoglobinopathies in pregnancy
- Blood Products – Management of Pregnant Woman Unable to Use Blood Products

9. RISK RATING

- High

10. NATIONAL STANDARD

- MS – Medication Safety

11. REFERENCES

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..../Appendices

APPENDIX 1

Ferinject®/Iron Infusion Information and Management Plan

You have been prescribed Ferinject® because you have low iron levels in your body and/or iron tablets/liquid have not worked, or have given you side effects. Please tell your doctor if you have an infection, asthma, eczema, allergies or any liver disorder.

What is Ferinject®?

Ferinject® is a form of iron medicine which is given directly into your vein (through a drip) to increase iron levels in your body. Iron is needed for the production of oxygen carrying red blood cells.

Can the infusion have any effects on my baby during pregnancy and breastfeeding?

Harmful effects have not been reported.

Can the infusion have any harmful effects on me?

Ferinject® is only recommended when the benefit is greater than the possible risks. Possible side effects (5:100) include headache, dizziness, high blood pressure, flushing, nausea, and skin reactions around the drip site. These can include pain in the drip site, bruising, and long lasting or permanent brown staining of the skin due to accidental leakage of the medicine. Other side effects (less than 1:100) include mild allergic reaction, numbness in the arm, racing heartbeat, low blood pressure, shortness of breath, vomiting, heartburn, stomach pain, constipation, diarrhoea, itchiness, hives, back pain, chest pain, high temperature and rash. A very rare side effect (less than 1:1000) is a serious allergic reaction (anaphylactic reaction).

How is Ferinject® given?

We administer Ferinject® in a medical setting due to the possible side effects. A full set of your observations will be taken before starting the infusion. If you are pregnant, we will listen to your baby's heartbeat. A cannula (drip) will be inserted into your arm and the infusion commenced. It is critical at this stage that you keep your arm still to prevent the cannula coming out. It is very important that you inform your care provider immediately if you think that the cannula has come out, or you are feeling pain/stinging/burning in your arm.

Will I have any after effects?

Sometimes women may feel a little tired, however, this should not prevent you driving home. Some women may have darker urine as about 5% of the iron is filtered through the kidneys the day after the infusion. If you experience any other side effects, please contact your health care provider immediately.

How long will the process take?

The whole process may take several hours and is done during normal business hours.

How long will it take for my iron levels to improve?

It will take 2-4 weeks for your iron levels to improve. Your iron levels will be checked 4-6 weeks after this infusion.

Should I continue to take oral iron?

Usually this is not needed but please check with your health care provider. It is important that you do not take any oral iron for five days after the infusion.

Ferinject® Infusion Checklist

To be completed by Health Care Provider following discussion with woman

Reason for IV Ferinject®	
Length of time and type of oral iron supplementation	
Symptoms of iron deficiency	
Iron infusion (Ferinject®)	Consent ☐ Information ☐
Most recent Haemoglobin(Hb) and Ferritin result	
Hb	Date:
Ferritin	Date:
Pre-pregnancy weight/current weight if not pregnant	
Ferinject® Prescription given (for outpatients)	Date:

APPENDIX 2

MANAGEMENT OF INFILTRATION/EXTRAVASATION OF INTRAVENOUS IRON THERAPY

Recognition

Signs and symptoms of infiltration and extravasation

Infiltration	Extravasation
• Tenderness/discomfort at cannula insertion site • Swelling above or below cannula insertion site • Taut skin above or below cannula insertion site • Fluid leak at cannula insertion site • Coolness/blanching around cannula insertion site • Numbness or tingling above or below cannula insertion site	• As for infiltration with the addition of: ○ Burning and/or stinging pain ○ Erythema followed by possible blistering, tissue necrosis and ulceration

Management

- Turn off infusion immediately.
- Do not disconnect infusion but remove the cannula immediately and abandon the infusion.
- Do not attempt another infusion.
- Apply a cold pack to the infiltrated site and elevate the affected limb.
- Do not rub site or apply pressure or heat pack.
- Reassure and provide full explanation to the woman.
- If iron staining is immediately visible, measure the site and arrange for hospital photographs to be taken. File photograph in patient's integrated clinical notes. This will aid ongoing monitoring of the woman.
- Assess and document the volume of infiltration by recording the volume of the infused fluid.
- Inform the woman's RMO so an assessment can be made of sensory deficit which could indicate nerve damage or compartment syndrome.
- Clearly document the management in the woman's integrated clinical notes.
- Further advice may be required from other specialities e.g. Dermatology, depending on woman's symptoms.
- Complete an IIMS form and forward to Pharmacy who will complete an ADR form.
- Arrange follow up as an outpatient where long term management can be discussed.

From "Management of Infiltration/Extravasation of Intravenous Iron Therapy" - King Edward Memorial Hospital for Women, Perth Western Australia

Government of Western Australia Department of Health. King Edward Memorial Hospital. Clinical Guidelines Obstetrics and Gynaecology: Management of infiltration/extravasation of intravenous iron therapy (2014). Retrieved from:
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