Procedure

Administration of Ferinject® (Ferric Carboxymaltose)- NSLHD

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Intranet location/s	Clinical – Pertaining All Areas – Blood/Transfusion Medicine
Summary	Ferinject® is to be ordered by VMO or staff specialist and administered safely via intravenous injection or intravenous infusion to iron deficient patients who meet the criteria specified in this procedure.
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Endorsed By	NSLHD Blood Management Committee
Sector/Service	NSLHD facilities where use of Ferinject® is approved
Audience	All staff involved in ordering, administration and management of iron within NSLHD
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Related Policy/s	Nil
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Status	

Administration of Ferinject® (Ferric Carboxymaltose)

SAFETY ALERT:
This procedure is for the administration of Ferinject® (ferric carboxymaltose) only. Do not use for any other form of iron. **Ensure you have the correct product**.
Maximum dose of Ferinject is **1000mg in 1 week**.

1. Scope of practice

1.1 Supply

a. Pharmacy

1.2 Prescription and consent

a. IPU approval required at some NSLHD facilities – please check your local Pharmacy Department prior to prescribing Ferinject®
b. Medical officer - the ordering of Ferinject® must be authorised by the Visiting Medical Officer or Staff Specialist caring for the patient.

2 Administration

2.1 Medical Officer

2.2 Registered Nurses/Midwives (RN/RM) assessed as competent to administer IV medications (as per facility requirements)

2.3 Enrolled Nurses (EN) assessed as competent to administer medication (as per facility requirements). The patient identification and verification process performed by the competent EN must be undertaken with a RN/RM in compliance with PD2012_064 The Administration of Medications by Enrolled Nurse

3 Monitoring

All of the above

Under the supervision of RN/RM:
Enrolled nurses
Assistants in nursing (Direct patient care)
Trainee Enrolled Nurses

4 Expected outcome

4.1 All patients receiving intravenous iron infusion within NSLHD will have the therapy administered in a safe, appropriate and timely manner in accordance with standard precautions and medication administration guidelines.

4.2 Prior to commencement of iron therapy, the patients' history and pathology results will be reviewed to ensure appropriate treatment.

5 Definitions

FERRIC CARBOXYMALTOSE is a non-dextran intravenous iron preparation containing iron in a stable ferric state as a complex of a polynuclear iron-hydroxide core with a carbohydrate ligand. The complex is designed to provide, in a controlled way, utilisable iron for the iron transport and storage proteins in the body (transferrin and ferritin, respectively). It is used to replenish iron stores when oral replacement is not adequate or tolerated.

IRON DEFICIENCY In symptomatic or high risk individuals, iron deficiency is generally diagnosed by a low ferritin (<30mcg/L) and/or low transferrin saturation (<20%), with or without a reduction in haemoglobin (Hb) (<100 g/L).[4]

6 Procedure

6.1 Policy statement

Intravenous iron infusion may be appropriate in:

- Iron deficiency anaemia where treatment with oral iron replacement has been unsuccessful due to intolerance or non-compliance with oral iron therapy.
- Iron deficiency anaemia where oral iron replacement is not indicated due to malabsorption/gastric surgery.
- A perioperative situation to rapidly increase haemoglobin as part of a blood management protocol, particularly to decrease or avoid the use of red cell transfusion.

In NSLHD Ferinject® is authorised for use in:

- Ambulatory care/day surgery units
- Obstetric patients
- Acute/Post Acute Care (APAC)
- Preoperative patients where there is a need to increase haemoglobin as part of blood management strategies to decrease or avoid the use of red cell transfusion.

IPU approval is required at some NSLHD facilities – please check your local Pharmacy Department prior to prescribing Ferinject®

<u>Contraindications:</u>

- Known hypersensitivity to Ferinject® or to any of its excipients
- Liver dysfunction
- Acute or chronic infection
- Pregnancy in first trimester
- Iron overload
- Anaemia not attributed to iron deficiency

<u>Adverse Reactions</u>

- Mild headache
- Dizziness
- Hypertension
- Nausea, abdominal pain, constipation, diarrhoea,
- Rash, pruritus, urticaria, erythema
- Injection site reaction
- Hyperferritinaemia,
- Hyposphophataemia

Intravenous ferric carboxymaltose infusions are to be administered only where direct nursing supervision is available.

Adrenaline and facilities for cardiopulmonary resuscitation must be readily available. Anaphylaxis reported with iron infusion was due to the use of iron dextran, which is no longer available. The potential for anaphylaxis to occur with iron carboxymaltose is very small, but still present.

Pregnancy (Category B3)
Iron deficiency occurring in the first trimester of pregnancy can in many cases be treated with oral iron. If the benefits of Ferinject® treatment are judged to outweigh the potential risk to the foetus, it is recommended that treatment is confined to the second and third trimester. The transfer of Ferinject® to human milk is negligible.[5]

6.2 Requirements

- Ferinject® vials (ferric carboxymaltose 500mg/10mL OR 100mg/2mL)
- Medical prescription for intravenous Ferinject® (ferric carboxymaltose), dose to be transfused (mg) and rate of infusion (mins)
- Informed written consent
- Patent IV access (18G cannula or larger)
- Sterile syringe or giving set
- Drawing-up needle
- General observation chart
- Sterile sodium chloride 0.9% for infusion
- Fluid balance chart
- Syringe driver or volumetric infusion pump, optional
- A current patient weight (kg) recorded on medication chart (NIMC)

- In pregnant women >26 weeks gestation a CTG (cardiotocography monitoring) is performed prior to commencing the infusion

6.3 **Dosage** (the cumulative iron dose required for repletion of iron using Ferinject® can be calculated using the Ganzoni Formula or the Simplified Method)

6.3.1 Ganzoni Formula

Cumulative iron dose (mg) = bodyweight (kg) x [target Hb – actual Hb g/L] x 0.24 + iron stores mg (mg)

Where:
Target Hb= 130g/L for body weight <35kg and 150g/L for body weight ≥35kg
Iron stores = 15 mg/kg body weight for body weight <35kg and 500mg for body weight ≥35kg
Round down to nearest 100mg if body weight ≤66kg and round up to nearest 100mg if body weight >66kg

Or

6.3.2 **Simplified Method** (for patients ≥ 35 kg)[1]

During pregnancy, this calculation should be based on the patients' **pre-pregnancy weight**.

Haemoglobin (Hb) g/L	Body weight 35 to < 70 kg	Body weight ≥ 70 kg
<100	1500mg	2000mg
≥100	1000mg	1500mg

Maximum tolerated single dose

A single dose of Ferinject® should not exceed 1000 mg of iron (20 mL) per day. Do not administer 1000 mg of iron (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.

6.4 Administration

A premedication with steroids or antihistamines is **not** routinely given.

Ferinject® must be administered by the intravenous route only.

Intravenous bolus injection

Ferinject® may be administered undiluted by intravenous injection up to a maximum single dose of 20mL (1000mg of iron) per day.

Dilution plan of Ferinject for intravenous drip infusion

Whilst Ferinject® may be administered undiluted, for ease of administration via infusion, dilution in sterile sodium chloride 0.9% solution can be performed as follows:

Ferric Carboxymaltose (Dose taken from undiluted 50mg/mL Ferinject® vial)		**Maximum amount of Sodium Chloride 0.9%** for infusion dilution	**Minimum administration time**
2 to 4 mL	(equiv 100-200mg iron)	50 mL	3 minutes
>4 to 10 mL	(equiv 200-500mg iron)	100 mL	6 minutes
>10 to 20 mL	(equiv >500-1000mg iron)	250 mL	15 minutes

Note: For stability reasons, dilutions to concentrations less than 2 mg iron/mL are not permissible. However, the concentration can be altered to be greater e.g. 20mL undiluted Ferinject® could be added to 100mL sodium chloride 0.9% (giving a 10mg/mL concentration) and administered over 15 minutes.

Administration:

- Dilute with sterile sodium chloride 0.9% only
- The nurse is to remain with the patient during the first 5 minutes of the infusion to observe for any adverse reactions.
- Caution should be exercised to avoid cannula displacement (after commencement of infusion) as this may cause brown discoloration and irritation of the skin.
- Run the infusion as per the above minimum administration times.
- Once diluted, use immediately.
- Discard any remaining product after use.
- Ensure NSW Health PD2012_012 labelling requirements are followed.

Observations:

- Baseline respiratory rate, pulse, blood pressure and temperature to be taken prior to commencement of infusion
- Repeat observations 5 minutes after commencement and at the end of the infusion.
- Occasionally, the infusion may need to be slowed because of local irritation.

Treatment for anaphylactic reaction:

- Turn off infusion,
- Initiate Clinical Emergency Response Team CERT) call and commence resuscitation.
- For mild reactions; give oral antihistamine (e.g. promethazine or loratadine), hydrocortisone and paracetamol as ordered by MO.
- Document adverse event in patient's medical record and submit IIMS and contact Transfusion Medicine CNC.
- Document on Medication Chart ADR section and add to electronic record ADR.

Follow up:

- Check haemoglobin and iron studies after 4-6 weeks to ascertain efficacy of treatment and need for additional treatment.
- It is imperative that the cause of iron deficiency is comprehensively investigated. If this does not take place during the patient's hospital admission, the medical officer must document the treatment of iron deficiency in the discharge summary and notify the patient's GP that follow up investigations for iron deficiency is required.

7 References

1. Ferinject® Product Information (Dec 2012), Vifor Pharma
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