CLINICAL GUIDELINES ID TAG	
Title:	***Protocol for Monofer® (Ferric Derisomaltose) Prescription and Administration***
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Directorate:	***Acute***
Date Uploaded:	17th April 2021
Review Date	***16th April 2024***
Clinical Guideline ID	CG0479[4]

Intravenous Iron Supplementation – Protocol for Monofer® Administration

Executive Summary

Iron deficiency is normally treated satisfactorily by the use of oral iron supplements. Circumstances when parenteral iron is recommended to replace iron stores include (i) when oral iron supplements are tolerated poorly leading to non-adherence; (ii) when there is insufficient absorption of iron from the gut due to an underlying illness such as renal disease or Crohn's disease; (iii) when the rate of iron loss exceeds the total absorption rate of iron from the gut or (iv) iron deficiency anaemia in patients scheduled to undergo major surgery within 6 weeks. This guidance applies to patients being treated in outpatient and inpatient settings. Monofer® is an intravenous iron preparation that offers the ability to administer the total iron requirements in one or two infusions. The ability to treat patients with their indicated iron load represents improved clinical treatment. As such the requirement for repeat infusions may be avoided or indeed the interval between courses extended.

Scope and Purpose

This guideline is relevant to all adult areas using Monofer® with the aim of ensuring safe and effective prescribing. This guideline is aimed at doctors, pharmacists and nurses involved in the administration of Monofer® to patients over 18 years of age.

Details of procedure to be followed

The prescriber will be able to use this guideline, along with basic patient details, to calculate the appropriate Monofer® dose for an individual patient. This should then be prescribed on the intravenous infusion prescription on the reverse of the fluid balance chart and referenced on the Kardex (in-patient or out-patient appropriate to the area where the patient will receive the infusion).

Once only medicines and pre-medications

Includes administration under Patient Group Direction (PGD)

If more than one Kardex in use, ensure 'once only' medicines are written on '1 of 2' Kardex, until once only section on that Kardex is complete

Patient Name: JOHN SMITH

H&C Number: 9876543210 DOB: 25-12-1945

Prescription							Administration		
Date	Medicine	Dose	Route	Time to be given (24 hour clock)	Signature	Print name Prof. no.	Given by	Time given (24 hour clock)	Pharmacist
6/1/21	MONOFER	see infusion chart	IV		A Doctor	A Doctor 1234-5678			

The infusion should be prepared and administered according to the prescription and the administration recorded.

Roles and Responsibilities

Medical staff

1. It is the admitting doctor's responsibility to ensure that treatment with intravenous iron is appropriate and other causes of anaemia have been excluded.
2. Review the contraindications and cautions to treatment. If any of these apply to the patient then there must be documentation of the risk-benefit balance.
3. It is the initiating doctor's responsibility to ensure that the appropriate monitoring (including haemoglobin and serum ferritin +/- transferrin saturation index) is performed, reviewed and patients followed up appropriately. The frequency of monitoring will need to be decided on a case-by case basis however repeat assessment should be no sooner than 3-4 weeks to detect optimal response .
4. It is the responsibility of the medical team to ensure that the iron infusion is prescribed.
5. It is the medical team's responsibility to ensure that the guideline is followed and specialist advice requested if required.

Nursing staff

1. It is the admitting nurse's responsibility to weigh the patient to enable accurate calculation of the iron dose.
2. Ensure that the infusion is prepared and administered safely and appropriately.
3. Ensure that patient observations are recorded before, during and after the infusion.
4. The nursing staff will inform the patient about the risks including allergy, skin infiltration and discolouration. Patients should be provided with a copy of Appendix C (Information for Patients Receiving Intravenous Iron Preparations). Patients will be asked to inform them immediately if they experience any pain at the cannula site.
5. It is the responsibility of the discharging nurse to ensure that patients are supplied with verbal and written information about the treatment.

Pharmacy Staff

1. It is the responsibility of the pharmacist to highlight any deviation from the guideline they identify to the patient's medical team.

Arrangements for Review of the Policy

Every three years.

References

1. Summary of Product Characteristics Monofer®. Available at www.medicines.org.uk Last updated 22/05/2020 accessed April 2021

Appendix A – Monofer® Prescribing and Administration Guideline

The purpose of this guideline is to advise medical and nursing staff on the prescribing and administration of Monofer®. Please refer to the Summary of Product Characteristics (available at www.medicines.org.uk) for full prescribing information.

Monofer® (ferric derisomaltose) is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.

Intravenous iron preparations must always be prescribed by brand.

1. Dosage and frequency of use

The dose of Monofer® is expressed in milligrams (mg) of elemental iron. The cumulative dose for repletion of iron using Monofer® is determined based on the patient's body weight and haemoglobin (Hb) level and must not be exceeded. It is the prescriber's responsibility to ensure this is done correctly. The following table should be used to determine the **cumulative iron dose**:

Simplified Dosing

Hb (g/L)	Body weight ≤ 50kg	Body weight 50kg to < 70kg	Body weight ≥ 70kg
≥ 100	500mg	1000mg	1500mg
< 100	500mg	1500mg	2000mg

Note:

- **Do not exceed maximum single dose of 20mg/kg per week by infusion**
- Doses exceeding 20 mg iron/kg body weight MUST be split in two administrations at least one week apart. This can be done by giving half of the dose on each day, or by giving up to 20mg/kg in the first infusion and the remainder in the second infusion. Where it may not be possible to administer a second infusion, give the 20mg/kg dose in the first administration and the second administration will be based on clinical judgement
- It is recommended to use the patient's ideal body weight for obese patients or pre-pregnancy weight for pregnant women. For all other patients use actual body weight. Ideal body weight may be calculated in a number of ways e.g. by calculating weight at BMI 25 i.e. ideal body weight = 25 x (height in m)^2

2. Patient monitoring before, during and after the infusion

- The haemoglobin and iron status (FERRITIN or TRANSFERRIN SATURATION INDEX) should be checked and recorded before the first dose is given.

- A set of observations (including blood pressure, pulse rate and temperature) and the NEWS score should be measured and recorded before administration. If the patient has any signs or symptoms of infection alert the appropriate doctor. They must decide whether or not is appropriate to delay giving the dose until any infection has resolved.

- Observations should be recorded after 5 minutes and 10 minutes following commencement of the infusion. A set of observations should also be checked on completion of the infusion and on discharge (minimum 30 minutes post-completion of infusion).

- The patient must be visible to nursing staff for the duration of the infusion.

3. Method of administration

Monofer® is available as ferric derisomaltose solution for injection containing 100mg iron in 1ml. This is available as 1ml, 5ml and 10ml ampoules. Doses should be diluted in 250mL sodium chloride 0.9% and administered by intravenous infusion. Only sodium chloride 0.9% should be used for dilution and flushing. The cannula must be flushed with 10ml sodium chloride 0.9% prior to infusion being commenced. Doses up to 1000mg must be administered over at least 15 minutes. Doses exceeding 1000mg must be administered over 30 minutes or more. No other therapeutic agents should be added. All infusions should be followed up with a 50ml flush of 0.9% sodium chloride.

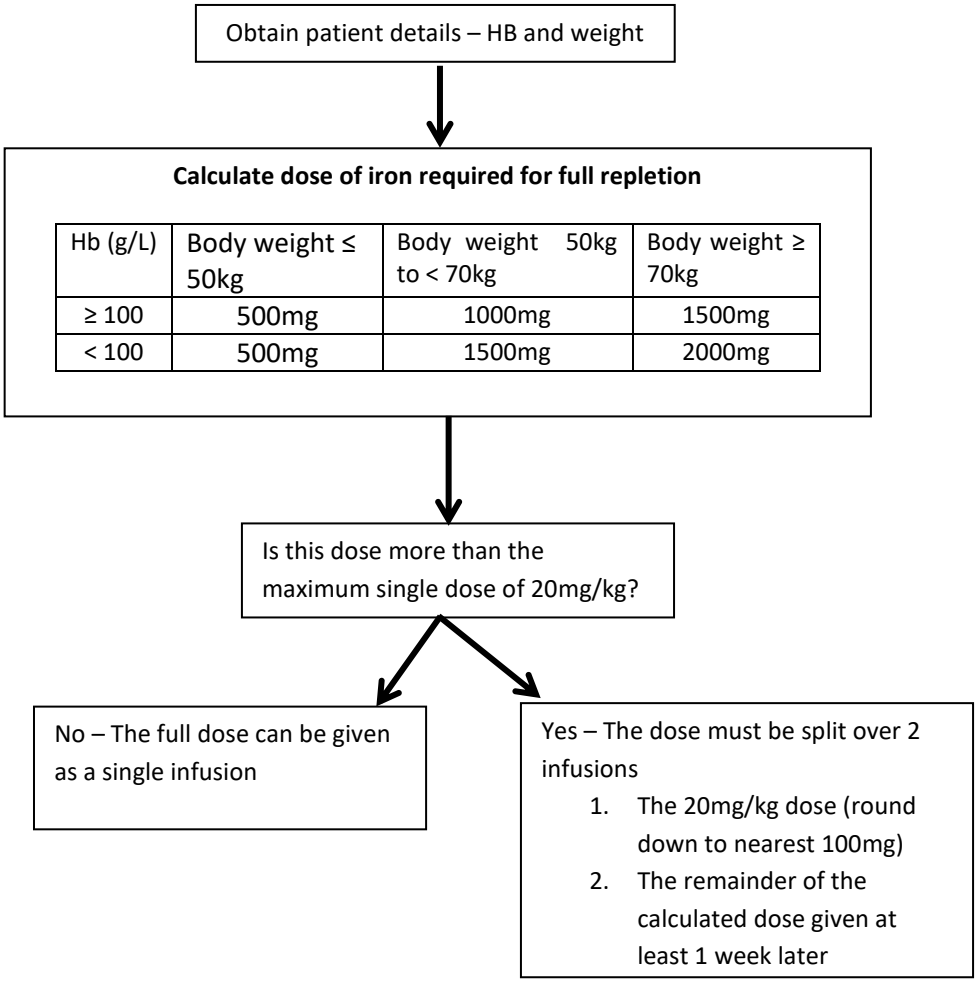
Ensure adrenaline (epinephrine) is available prior to administration. As with all IV preparations, acute anaphylaxis may occur with MONOFER®, although this is rare (≥1/10000 to <1/1000). It usually occurs in the first few minutes after the administration, is generally characterised by the sudden onset of respiratory difficulty and/or cardiovascular collapse and requires treatment with IM ADRENALINE. Other less severe manifestations of immediate hypersensitivity are uncommon (≥1/1000 to <1/100). These include urticaria, itching, and shivering. Rash and nausea are common (≥1/100 to <1/10).

Milder allergic reactions should be managed by stopping the administration of MONOFER®. IV steroids / antihistamine may be needed in some cases and the patient should be reviewed by a doctor. The infusion can then be restarted at a slower rate and the patient closely observed. Mild reactions such as nausea or feeling faint usually warrant observation only. Appendix D outlines the steps to take in for a potential infusion reaction.

The patient should be observed for 30minutes following completion of the infusion.

Appendix B

Dose Calculation Flow Chart



- It is recommended to use the patient's ideal body weight for obese patients or pre-pregnancy weight for pregnant women. For all other patients use actual body weight. Ideal body weight may be calculated in a number of ways e.g. by calculating weight at BMI 25 i.e. ideal body weight = 25 * (height in m)^2

Appendix C

Information for Patients Receiving Intravenous Iron Preparations

Your medical team have recommended intravenous iron to treat your anaemia / low blood count. This will be given as an infusion/drip over 15 or 30 minutes. Please read the following information prior to your treatment and if you have any questions let the nurse caring for you know.

1. Intravenous iron is used to treat a low blood count due to a low amount of iron in your body. This may have occurred due to low amounts of iron in your diet, a problem with your body's ability to absorb and use iron or be as a result of blood loss.
2. Intravenous iron is a highly effective method to replenish your body's stores of iron and hopefully allow you to increase your blood count over the coming days and weeks.
3. Intravenous iron allows a much larger dose of iron to be given than iron in tablet form.
4. All medication carries a risk of side effects and reaction. Prior to receiving your treatment it is important you are aware of the side effects / risks of intravenous iron. The nurse caring for you will ask if you understand the information below and are content to proceed prior to you treatment.

Side Effects of Intravenous Iron Therapy

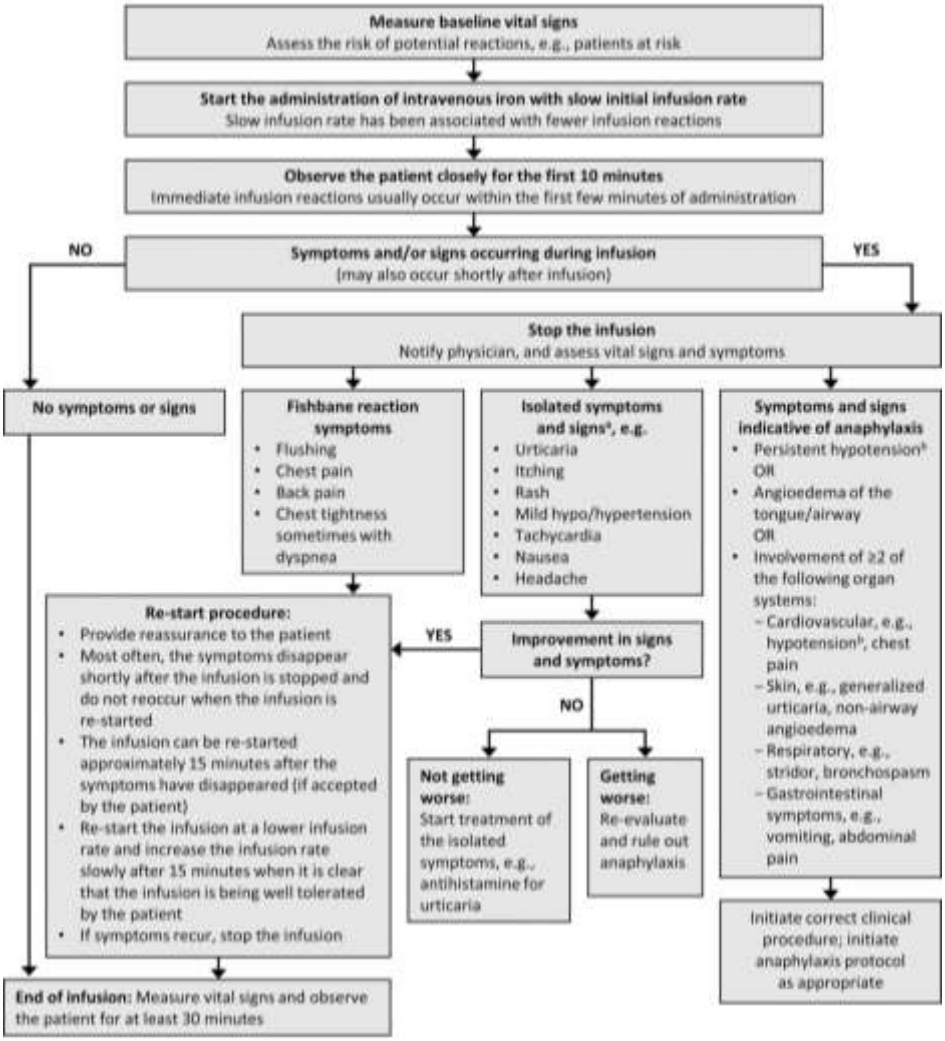
1. Intravenous iron has a good safety profile and is an effective therapy for treatment of iron deficiency anaemia. Common side effects include headache, dizziness, flushing, nausea and a reaction at the site of injection/infusion. You will be monitored while intravenous iron is being administered and for 30 minutes after your treatment has been completed.
2. Staining – If your cannula was to displace from your vein during treatment the drug could be deposited in your skin rather than into your bloodstream. This could result in a permanent brown stain to the skin. If you notice pain at the injection site during your treatment please inform the nurse caring for you immediately. This will minimise any such risk.
3. Change in total body skin colour – This is an extremely rare occurrence. It has been reported that some patients noted their skin to become darker (like a sun tan) for a period of weeks after treatment with intravenous iron. This was not permanent and resolved after a number of weeks.
4. Allergy – Historically intravenous iron preparations carried a risk of allergy (ranging from a mild reaction like itchy skin through to anaphylaxis that could be life threatening). With today's modern iron preparation anaphylaxis is rare (1 in a 1000 to 1 in a 10,000 risk). Please inform the nurse caring for you immediately if you experience any of the following during your treatment (swelling of lips, tongue, face or throat, shortness of breath, itching, a feeling of all over body heat, heart racing heat or faint like symptoms)
5. Delayed reaction – Although uncommon, some patients may experience muscle or joint pains and fever in the days after treatment. This usually lasts two to four days and can be managed with simple painkillers like paracetamol.

Appendix D

Algorithm for IV Iron Immediate Infusion Reaction

Preoperative Assessment Department IV Iron Service

Algorithm for the Management of Immediate Infusion Reactions



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