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| **Clinical Guideline for the administration of Parenteral Iron Infusions (Monofer) in Community Hospitals day case patients and for appropriate RDE ambulatory patients** |

**SUMMARY**

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| This guideline outlines the process to support the appropriate administration of Iron infusions in Community Hospitals (these guidelines may also be appropriate for ambulatory patients at the RDE).  Parenteral Iron is indicated for patients with iron deficiency anaemia when oral Iron therapy is unsuccessful or not tolerated.  As per these guidelines intravenous iron is only to be administered as an infusion and not as an intravenous bolus injection. |

**KEY POINTS**

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| **Referrals**  Patients appropriate for iron infusions in Community Hospitals are identified either through:   * General Practitioner (GP) direct request * Secondary Care consultant request * Hospital Transfusion Team discussion with GP after review of a blood transfusion request   Referrals for Community Hospital day transfusions are received by completing the booking form and emailing it to [rde-tr.communitytransfusions@nhs.net](mailto:rde-tr.communitytransfusions@nhs.net)  or by contacting day transfusions on 01395 519957 (between the hours of 9-3pm Monday to Friday)  Facilities for cardiopulmonary resuscitation must be available.    **Prescribing**  Monofer is the only parenteral iron product to be prescribed in Community Hospitals as per recommendations in the North and East Devon Formulary  <https://northeast.devonformularyguidance.nhs.uk/formulary/chapters/9.-blood-and-nutrition/favicon.ico>  The Monofer dose prescribed is based on the individual patient’s needs including weight and iron deficit. The prescription must be clearly written and signed on a Fluid (Additive Drug) Prescription Medication Sheet.  **Supplies**  Parenteral iron supplies are dispensed on a named patient basis by the RDE Pharmacy department.  **Administration**  Patient observations should be stable prior to administration.  The patient should be afebrile and not acutely unwell.  All patients should be closely monitored during the infusion for signs of hypersensitivity and extravasation during and for at least 30 minutes after every administration of Monofer and observations taken as per page 6 of this guideline  **Follow up**  GPs should repeat full blood count, ferritin and mean corpuscular volume (MCV) at 6 weeks post transfusion to review the efficacy of the iron transfusion.  **Audit**  Activity of iron transfusions in Community Hospitals will be audited annually. |

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# 1. INTRODUCTION / BACKGOUND

Anaemia occurs when red blood cells (RBC) production is decreased, RBC destruction is accelerated, or RBCs are lost due to bleeding. The most common type of anaemia is Iron Deficiency Anaemia, with a prevalence of 2-5% in adult men and post-menopausal women.

Parenteral Iron is indicated for patients with Iron deficiency anaemia when oral Iron therapy is unsuccessful or not tolerated.

Patients with Iron Deficient Anaemia and a functioning bone marrow need iron rather than blood. An average infusion of intravenous iron is 1gram of iron; this is equivalent to the amount of iron in 4 units of packed red cells

The first treatment choice is to use oral iron but intravenous iron should be considered for patients:

Who cannot tolerate or are unable to take oral iron

* For whom oral iron has been ineffective
* In whom oral iron is likely to be ineffective e.g.in patients with chronic renal disease or anaemia due to chronic disease or inflammation.
* Where there is not sufficient time for oral iron to work, eg pre operatively

Intravenous iron will improve the haemoglobin in iron deficient patients in 7 to 14 days. Blood transfusion may be needed to relieve symptoms of anaemia such as angina, intermittent claudication, shortness of breath that require correcting quickly. In these patients often a single unit of blood can overcome the acute symptoms and this can be backed up by an iron infusion at the same time.

Parenteral iron infusions can be administered for ambulatory patients in Tiverton or Sidmouth Community Hospitals. These Community Hospitals have been risk assessed and have facilities for the management of anaphylaxis and cardiopulmonary resuscitation and have staff competent to administer intravenous infusions and manage emergency situations.

As per these guidelines intravenous iron is only to be administered as an infusion and not as an intravenous bolus injection.

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# 2. MAIN BODY OF GUIDELINE

**Referrals**

Patients appropriate for iron infusions in Community Hospitals are identified either through:

* GP direct request
* Secondary Care consultant request
* Hospital Transfusion Team discussion with GP after review of a blood transfusion request. The Hospital Transfusion Team screen all Primary Care requests for blood transfusions for iron deficiency anaemia and if possible iron deficiency is identified, feedback is given to the GP that the patient may be suitable for oral or iv iron.

Referrals for Community Hospital day transfusions are received by completing the booking form and emailing to rde-tr.communitytransfusions@nhs.net

or by contacting day transfusions on 01395 519957 (between the hours of 9-3pm Monday to Friday)

**Serious hypersensitivity reactions, including life-threatening and fatal anaphylactic reactions, have been reported in patients receiving intravenous iron therefore facilities for cardiopulmonary resuscitation including oxygen and suction must be available at the Community Hospital and access to anaphylaxis equipment including adrenaline should be available in the treatment area.**

**Staff administering intravenous iron infusions must be competent and up to date with anaphylaxis, resuscitation and intravenous drug administration training.**

**Prescribing**

The GP or the F2 prescriber does not have to be present in the Community Hospital when the infusion is taking place but does need to be accountable for appropriate prescribing and safe administration.

Monofer is the **only** parenteral iron product to be prescribed as per recommendations in the Joint North and East Devon Formulary.

<https://hub.exe.nhs.uk/search/?q=joint+formulary>

Contra indications to Monofer as per the Summary of Product Characteristics (SPC)

[Monofer 100mg/ml solution for injection/infusion - Summary of Product Characteristics (SPC) - (eMC)](http://www.medicines.org.uk/emc/medicine/23669)

Include:

* Non-iron deficiency anaemia.
* Iron overload or disturbances in utilisation of iron.
* Hypersensitivity to any of the ingredients.
* Patients with a history of asthma, allergic eczema or other atopic allergy.
* Decompensated liver cirrhosis and hepatitis.
* Rheumatoid arthritis with symptoms or signs of active inflammation
* It is not recommended to administer oral iron until 5 days after the last iron infusion

The risk of hypersensitivity is increased in patients with known allergies, immune or inflammatory conditions (e.g. Systemic lupus erythematosus (SLE) and rheumatoid arthritis); or those with severe asthma, eczema or other atopic allergy. In these patients IV iron products should only be used if the benefits are clearly judged to outweigh the risks.

The Monofer dose prescribed by the GP or F2 should be based on the individual patient’s needs including weight and iron deficit.

In Community Hospitals 1gm should be prescribed unless the patient is

* under 50Kg in weight
* under 160cm in height

In these cases the monofer calculator is used and weight and height are required (Appendix 1)

All prescriptions are checked through pharmacy and ordered as individual patient prescriptions. (See note re supplies below)

The individual prescription should be clearly written and signed on a Fluid (Additive Drug) Prescription Medication Sheet. and include:

* Patients name and weight (Height if under 50kg in weight)
* Allergy status
* Monofer Dose written in mg
* Route of administration
* Dilution - Monofer must only be diluted in Normal Saline (recommended 100mls)
* Infusion date and time
* Infusion duration

Doses up 1000mg should be infused over 30minutes

**Supplies**

Parenteral iron supplies should be dispensed on a named patient basis by the RDE

Four 500mg vials are in stock for use within the transfusion service at Sidmouth hospital these are only to be used in a scenario where a patient needs to attend for an iron infusion urgently and there isn't enough time to pre-prescribe.

**Administration**

On the day of the Monofer infusion, patients must be infection free.

Prescription checked against up to date weight and height.

Patients should be verbally informed of the risks of Monofer infusions and recognition of any adverse reactions and given a patient information leaflet (Appendix 3).

Patient’s verbal consent should be documented.

Monofer should only be administered through an appropriate size IV cannula (22G/20G/18G) and delivered via an IV pump (Braun Infusomat Space). The IV site and the Visual Infusion Phlebitis (VIP) score should be recorded and site observed for any signs of extravasation (leakage of drug into the tissue). The cannula should be flushed pre and post transfusion with Normal Saline.

All patients should be closely monitored for signs of hypersensitivity during and for at least 30 minutes after every administration of Monofer.

Baseline observations and early warning score should be completed prior to the infusion being commenced and again on completion.

On completion of infusion patients should then be observed for adverse effects for at least a further 30 minutes before being discharged and information leaflet given (Appendix 2).

**Main Complications**

Extravasation

Extravasation of all forms of IV iron therapy may result in permanent skin pigmentation and skin irritation. Iron should therefore only be transfused via larger visible veins and if any symptoms or signs of extravasation are suspected the infusion should be discontinued immediately and the GP/F2 informed. Treatment is dependent on the severity of the extravasation and should be determined before removal of the cannula; advice may be sought from the RD&E Trust IV Policy and the RDE Pharmacy Department. All incidents of extravasation should be documented in the patient’s notes and a datix incident form completed.

Anaphylaxis (Appendix 3)

* **This is an emergency**
* Stop infusion
* Call for help
* Get adrenaline 1:1000 injection
* Use ABC approach
* Give 0.5ml of 1:1000 adrenaline IM

In the event of the patient suffering an adverse drug reaction, treatment should be stopped immediately and appropriate management initiated. The F2/GP and the nurse in charge must be informed as soon as possible after the patient’s needs have been addressed. The incident must be recorded in the patient record indicating the actions taken, highlighting the medication which prompted the adverse reaction. It should be reported on Datix in accordance with the Trusts Incident reporting policy. A Medicines and Healthcare products Regulatory Agency (MHRA) ‘Yellowcard’ should be completed, details are found in the British National Formulary (BNF) and online at: <https://yellowcard.mhra.gov.uk/>

**Follow up**

GPs should repeat full blood count, ferritin and MCV at 6 weeks post transfusion to review the efficacy of the iron transfusion.

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# 3. MONITORING COMPLIANCE WITH THIS GUIDELINE

Iron infusions carried out in Community Hospital will be audited annually. Results will be shared with General Practice, Community Hospital staff and the Hospital Transfusion Team

# 4. ASSOCIATED CLINICAL GUIDELINES/ POLICIES/ PROCEDURES/ REFERENCES

<https://hub.exe.nhs.uk/search/?q=medusa>

MHRA Drug Safety Update. Volume 6; Issue 1 August 2013. Intravenous iron and serious hypersensitivity reactions; new strengthened recommendations to manage and minimise risk.

National Institute for Health and Care Excellence Blood transfusion Guidelines (Nov 2015)

RCN Iron Deficiency and Anaemia in Adults (June 2015) RCN guidance for nursing staff

Resuscitation Council (UK) [www.resus.org.uk](http://www.resus.org.uk)

University College London Hospitals Injectable Medicines Guide at:

[UCL Hospitals Injectable Medicines Administration Guide Online: Home](http://www.uclhguide.com/subscriber/uid=4596/?authstatuscode=202)

# 5. PUBLICATION DETAILS

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**Appendix 1**

**Use the following link to access the calculator**

<https://hub.exe.nhs.uk/search/?q=monofer+calculator>

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| --- | --- | --- | --- |
| **Monofer (iron (III) isomaltoside 1000) dosing calculator** | | | |
|  |  |  | **Range permitted** |
| **Sex** | Female | | Male, Female |
| **Height** |  | cm | 150 - 250 cm |
| **Weight** |  | kg | 30 - 400 kg |
| **Ideal body weight** |  | kg |  |
| **Weight used** |  | kg |  |
|  |  |  |  |
| **Current haemoglobin** |  | g/L | 30 - 150 g/L |
| **Target haemoglobin** |  | g/L | 100 - 150 g/L |
|  |  |  |  |
| **Total dose required** |  | mg Monofer |  |
|  |  |  |  |
| **Dose for first infusion** |  | mg Monofer |  |
| **Minimum time for first infusion** |  | minutes |  |
|  |  |  |  |
| **Dose for second infusion** |  | mg Monofer |  |
| **Minimum time for second infusion** |  | minutes |  |

**Appendix 2**

**Patient Information**

**Intravenous (IV) iron therapy**

**What is Iron?**

Iron is an essential nutrient for your body. It is an important part of haemoglobin (Hb), the red pigment which gives blood its colour and which carries oxygen around your body. Iron deficiency is a common cause for anaemia (low haemoglobin levels)

**Why do I need Iron infusions?**

Your blood results have shown that the amount of iron you have in your blood is low.

You need iron so your body can make new haemoglobin and red blood cells to carry the oxygen your body requires.

Treatment usually involves taking iron tablets and changing your diet to increase your iron levels. Although if required iron can also be given by intravenous infusion (fluid direct in to your blood stream).

**What are the likely benefits of Iron infusions?**

Your iron levels will increase and this will improve your haemoglobin levels and help your anaemia. You may notice that you are less tired, have more energy, better concentration and become less breathless when taking exercise.

**How will the iron be administered?**

You will receive the iron by intravenous (IV) infusion – via a drip and pump into a vein in your arm, which takes approximately 30 minutes depending on the amount of iron administered.

**Who is not suitable for intravenous iron?**

People who are known to be sensitive (allergic) to any iron preparations intended for intramuscular or intravenous administration.

People who are known to have liver damage.

People who have any acute or chronic infections.

**What are the risks / side effects of intravenous iron?**

Side effects are usually mild, but it is important to report any unusual or unexpected symptoms you may be feeling to the nurse looking after you.

The most common reaction is a metallic taste in your mouth. This normally disappears within 15 minutes.

You may also feel light headed, sick or dizzy.

Other rare side effects that you may notice following treatment of iron include lowering of blood pressure, tingling or numbness of the limbs, abdominal discomfort, muscular aches and pains, fever, rashes, skin flushing, swelling of the hands and feet and very rarely, anaphylactic like reactions (e.g. paleness, swollen lips, itchiness, weakness, sweating, dizziness, feeling of tightness in the chest, chest pain, fast pulse, difficulty in breathing). Please see details below of who to contact once you have left the hospital.

**How long will my treatment last?**

The iron infusion will be given over 30 minutes to an hour and you will need to stay in hospital for 30 minutes after the infusion has finished; so expect to be in hospital for about 2 hours

**What happens after my treatment?**

If you were taking iron tablets before your infusion please check with your GP as they are not normally needed after having IV iron

Your GP will ask you to return four weeks after you have had your IV iron to check how well you've responded to the treatment and to have a repeat blood test to check your haemoglobin levels.

**Who to contact for assistance**

**To obtain assistance in the event of a problem following your iron infusion, please contact:** (this section to be explained to the patient and completed by staff on discharge)

**GP Surgery-**

**Tel no-**

**Date and time of Iron infusion-**

**In the rare event of an emergency (life threatening, for example difficulty with breathing), call 999 for an ambulance and bring this leaflet into hospital with you**

If you would like further information or advice regarding Iron infusions please discuss this with your GP or Hospital Doctor/Nurse

**Appendix 3**

