Southern Health and Social Care Trust

TITLE	**Management of Iron Deficiency in Heart Failure (HF): Ferric Derisomaltose**
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Management of Iron Deficiency in Heart Failure (HF) using Ferric Derisomaltose

Context

Iron deficiency (ID) is common in patients with heart failure (HF) and is independently associated with reduced exercise capacity, recurrent HF hospitalizations, and high cardiovascular and all-cause mortality.

ID, which can be present independently of anaemia, is present in up to 55% of chronic HF patients and in up to 80% of those with acute. Although the exact cause of iron deficiency in HF remains unknown, it may be caused by increased loss, reduced intake or absorption (i.e. malnutrition, gut congestion) and/or impaired iron metabolism caused by the chronic inflammatory activation of HF.

Oral iron therapy is not effective in iron repletion in HF and is not recommended for the treatment of iron deficiency in patients with HF. Intravenous iron supplementation using is recommended (ESC 2023).

Recommendation Table 5 — Recommendations for the management of iron deficiency in patients with heart failure

Recommendations	Class[a]	Level[b]
Intravenous iron supplementation is recommended in symptomatic patients with HFrEF and HFmrEF, and iron deficiency, to alleviate HF symptoms and improve quality of life.[c] 12,41,47–49	I	A
Intravenous iron supplementation with ferric carboxymaltose or ferric derisomaltose should be considered in symptomatic patients with HFrEF and HFmrEF, and iron deficiency, to reduce the risk of HF hospitalization.[c] 12,41,43–46	IIa	A

This document outlines the use of Ferric Derisomaltose for the treatment of ID in HF.

Definition of Iron Deficiency:

Ferritin <100 ug/L (absolute iron deficiency)

OR

Ferritin 100 – 299 ug/L with Transferrin Saturation (TSAT) <20%

Screening

All patients with a diagnosis of HF should be regularly screened at first assessment and at least six monthly intervals for anaemia and ID with full blood count, serum ferritin concentration, and TSAT.

The detection of anaemia and/or ferritin <30 ug/L should prompt appropriate investigation to define their cause. The primary physician / GP should be notified so that prompt investigation can take place under their care.

Patients to consider for IV iron replacement with Ferric Derisomaltose

1. Patients with **LVEF <45%,** NYHA II - IV and and ID (defined as serum ferritin <100 ug/L **OR** serum ferritin 100 - 299 ug/L with TSAT <20%.)

2. Any patient with a diagnosis of HF who falls outside indications 1 but who may benefit from treatment on the recommendations of a HF consultant.

Exclusion Criteria/ Contraindications:

- Hypersensitivity to active substance (Ferric Derisomaltose) or any of its excipients.
- Hypersensitivity to other parenteral iron products.
- Non-iron deficiency anaemia (e.g. haemolytic anaemia).
- Iron overload or disturbances in utilisation of iron.
- Decompensated liver cirrhosis.
- Active ongoing bacteraemia.
- First trimester pregnancy.
- Second and third trimester pregnancy (can consider if benefit outweighs risk and following discussion with HF Consultant).

Prescribing Considerations

Summary of Product Characteristics for Ferric Derisomaltose are available at www.medicines.org.uk

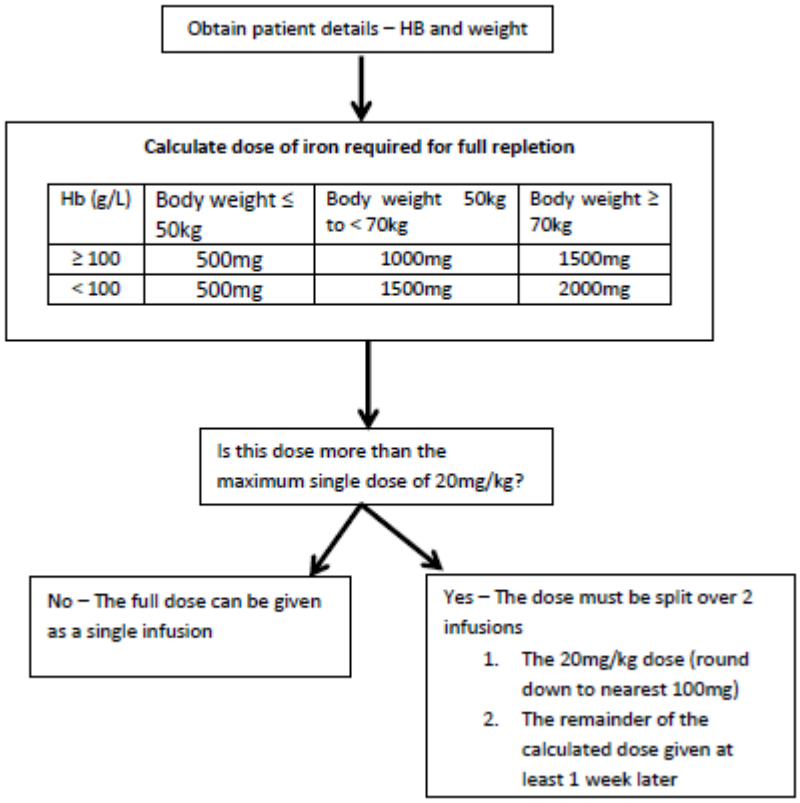
Dosing of Ferric Derisomaltose is determined based on the patient's body weight and haemoglobin (Hb) level.

The following baseline bloods / measurements should be reserved before prescribing:

- Full blood count
- Ferritin
- Iron profile
- Weight (in kg)

Dosing Schedule

Ferric Derisomaltose Dose Calculation Flow Chart



The maximum single dose of Ferric Derisomaltose **should not exceed 20 mg of iron per kg** of patient body weight.

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.

Ferric Derisomaltose should be prescribed as a 'stat' dose on the patient's drug kardex and should also be prescribed on a fluid balance chart.

Preparation

Ferric Derisomaltose is administered via an intravenous infusion. It is available as solution for injection containing 100mg iron in 1ml. This is available as 1ml, 5ml and 10ml ampoules.

Ferric Derisomaltose is administed by intravenous infusion, diluted in 100ml of sodium chloride 0.9%. Only sodium chloride 0.9% should be used for dilution and flushing.

For stability reasons, Ferric derisomaltose should not be diluted to concentrations less than 1 mg iron/ml (not including the volume of the Ferric derisomaltose solution) and never diluted in more than 500 ml.

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.

Pre-Administration

Patients should be provided with written information about the reason for their infusion and the associated risks. A record of this should be kept in their notes. A copy of this can be found in Appendix 1.

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.

During and Post Administration

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.

As with all IV preparations, acute anaphylaxis may occur with Ferric Derisomaltose. Ensure adrenaline (epinephrine) is available prior to administration.

Acute anaphylaxis may occur with Ferric Derisomaltose, 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 Ferric Derisomaltose. 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.

Iron deposition in the tissues can be irreversible and cause skin staining. The infusion site must be monitored to ensure that the cannula is correctly positioned for the duration of the infusion.

Mild reactions such as nausea or feeling faint usually warrant observation only.

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

Onwards Monitoring of Iron Levels

Hb, ferritin and iron studies should be measured 4 – 6 weeks after the last infusion. If the patient remains iron deplete, further dosing should be discussed with the HF Consultant.

If IV iron is given at a day clinical centre site, the day clinical centre must complete the post infusion details on the referral form and email a copy of this along with the discharge letter to heart.failureservices@southerntrust.hscni.net

On recepit, the heart failure nurses must arrange appopriately timed bloods. The GP should not be asked to check post iron infusion bloods.

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Appendix 1:

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.

I confirm that the above information has been given to/explained to the patient prior to treatment	PRINT NAME SIGNATURE DATE

REFERENCES

ESC 2023 https://doi.org/10.1093/eurheartj/ehad195

CG0479[6] Protocol for Ferric Derisomaltose Prescription and Administration Southern Trust Guidelines | Southern Trust Guidelines (hscni.net)