Iron Therapy for Iron Deficiency in Heart failure UHL Cardiology Guideline

Change Description	Reason for Change
□ Formalise and standardise care	□ Trust requirement/ First SOP specific to heart failure

APPROVERS	POSITION	NAME
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Introduction and Background:

This SOP covers the management of Iron deficiency (ID) in patients with heart failure. Iron deficiency is a common complication of heart failure, with a prevalence of around 50% irrespective of left ventricular function. The latest international guidance recommends treatment of ID in the context of Heart Failure with a reduced ejection fraction (HFrEF). ID is strongly associated with reduction in quality of life (QOL), reduced exercise performance, disease severity and prognosis. ID is confirmed with a serum ferritin level of <100 Mcg/L or 100-299Mcg/L or transaturation of less than 20%. The pathophysiology behind the high incidence is complex and influenced by factors such as renal impairment, medications and in particular ID (ESC Guidance 2016). This has been demonstrated in both the CONFIRM-HF study (2014) and AFFIRM-AHF trial (2020) showing improvement in symptoms.

NICE have not adopted these recommendations, there are still unanswered questions regards long term effects and therefore awaiting further trials prior to making recommendations.

Scope

This standard operating procedure will be used in the UHL Trust Heart Failure unit where intravenous iron

may be administered. It is to be used by registered nursing and medical staff with appropriate experience.

1) Clinical guidelines are 'guidelines' only. The interpretation and application of clinical guidelines will remain the responsibility of the individual practitioner. If in doubt, consult a senior colleague or expert.

Recommendations:

NB: There is emerging evidence regarding the utility of intravenous iron replacement in other chronic disease states. The European Society of Cardiology now recommends the use of IV iron for symptomatic patients with heart failure and reduced ejection fraction (HFrEF, defined as an ejection fraction of <40%) if their ferritin is <100 ug/L or with a ferritin of 100-299 ug/L and a TSAT of <20% in order to alleviate symptoms, improve exercise capacity and quality of life. Given the increased prevalence of heart failure in the CKD population, administration of IV iron may therefore be indicated for reasons other than CKD-related anaemia.(Please also see SOP for CKD and Iron deficiency & Anaemia SOP)

Intravenous iron for patients with heart failure with reduced ejection fraction

This is recommended in the following:

1. Patients with an ejection fraction of <40%
2. Iron deficiency is confirmed with a serum ferritin level of <100Mcg/L or ferritin of <299Mcg/L or a Transaturation of <20%
3. Symptomatically short of breath and fatigued with NYHA II-IV symptoms.

Dose of Iron Carboxymaltose (Ferinject)

Iron carboxymaltose (Ferinject) infusion - Often patients need 2 infusions to receive full dose.

To be prescribed by Consultant Cardiologist or Heart failure ANP.

Hb	Patient body weight	
g/L	35kg to <70kg	70kg and above
<100	1500mg	2000mg
100 to <140	1000mg	1500mg

(For up to date provider information please see Medusa & Summary of Product Characteristics (SPC) for further guidance on administration)

An individual prescription for Ferinject will be pre-ordered for patient and stored in a locked cupboard as per

trust/manufacturers drugs storage guidance.

Initiating IV Iron

In August 2013, the MHRA reviewed the evidence for serious reactions to IV iron and concluded that there was no evidence to support the use of an initial test dose of IV iron. This practice has now been discontinued. There is no requirement for a doctor to be in attendance when the first dose of iron is administered.

If any complications/reaction during procedure i.e temperature, please monitor/document on iron pathway, ensure observations/EWS completed and patient stable prior to discharge (see appendix 1).

In case of anaphylaxis please refer to anaphylaxis procedure.

Post Iron infusion

Patient should omit oral iron supplement for 7 days post IV Iron infusion.

Patient should have a blood test to check Bone 2 weeks post each Iron infusion to check Phosphate levels to check for hypophosphatemia and further infusions should NOT be given until phosphate levels corrected.

6 weeks post full dose administered repeat FBC/Ferritin and Bone should be taken prior to discharge to GP.

Anaphylaxis

Experience has shown that Iron carboxymaltose (Ferinject) is associated with a very low risk of anaphylactic reactions. Any reactions are more likely to be due to rapid release of free iron. The prescribing doctor and administering nurse must confirm with the case records and with the patient that there is no history of reactions to IV iron. Infusion must be given in an area with cardiac arrest trolley with anaphylaxis box. This is situated on ward 16/17 GGH for the Heart Failure service accessible from the clinic area, (situated on ward 17 opposite side room 2 next to nurses station & ward 16 opposite side room 1 next to nurses station).

Based on local experience and expert opinion, any adverse reaction of the preparations is a contraindication to administering any other formulation of IV iron.

Governance and Audit:
Reporting of side effects and adverse reactions as per trust guidelines/policy, Datix and yellow card reporting. HRG's either: FD04 (If iron deficiency documented) OR SA04 (if iron deficiency anaemia documented)
References to other standards, alerts and procedures:
Anker S D., et al. (2009) **Ferric Carboxymaltose in patients with Heart Failure and Iron Deficiency.** *The New England Journal of medicine 361 pp 2436-2448*. Eltayeb, Mohammed., Ashok, Vishnu., Squire, Iain. (2021) **Prevalence, causes, diagnosis and guidelines for treatment.** *British Journal of Cardiology, Vol.28, Supplement 1: S3-S6.* Kocyigit, Duygu & Gurses. (2016) **Iron deficiency and its treatment in heart failure: Indications and effect on prognosis.** *European Society of Cardiology, Vol.14, No 30.* Ponikowski, Piotr., Voors, Adriaan A., Anker, Stefan D., (2016) **ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure.** *European Society of Cardiology.* Ponikowski, Piotr., Voors, Adriaan A., Anker, Stefan D., (2020) **(AFFIRM-AHF Trial) Ferric carboxymaltose for iron deficiency at discharge after acute heart failure: a multicentre, double-blind, randomised, controlled trial**. *The Lancet Vol 20.* Ponikowski, Piotr., Van Veldhuisen, Dirk. J., Comin-Colet, Josep., (2014) **(CONFIRM-HF Study) Rationale and design of the CONFIRM-HF study: a double-bind, randomised, placebo-controlled study to access the effects of intravenous ferric carboxymaltose on functional capacity in patients with chronic heart failure and iron deficiency.** *The European Journal of Heart Failure Vol 1 pp52-58*
END

Appendix 1

Administration of intravenous iron carboxymaltose (Ferinject) infusion.

Competency to administer IV iron

• IV iron must be given by a registered nurse who holds an 'IV certificate' and demonstrates competency in carrying out this procedure (NMC scope of Professional Practice) accordance with the UHL Preparation and Administration of Intravenous Medications and Fluids to Adults, Babies, Children and Young People.

• Facilities for resuscitation must be available including supplies of antihistamines, corticosteroids and adrenaline for parenteral use; these must be prescribed routinely for all patients prescribed IV iron on the drug chart, so that these drugs may be administered intramuscularly or intravenously by nursing staff in the rare of event of an anaphylactic reaction

• Record the patient's temperature and assess for signs of infection. Concurrent infection is a contraindication for intravenous iron. Take appropriate advice if abnormalities detected

• Wash hands with liquid soap and water; cover any visible broken skin with a waterproof dressing

• If IV iron is omitted for any reason this must be noted in the patients' communication sheet and on the drug chart.

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Procedure for administering iron carboxymaltose (Ferinject)

1. **Equipment required**

Alcohol based hand rub
100mg and/or 500mg vials of iron according to dose Sodium chloride 0.9% 250mls minibag
Tourniquet
1 x blue needles 1 x 10ml syringe
1 x IV additive label
1 x volumetric giving set 1 x volumetric pump

2**. Procedure**

• Ensure the prescription is correct, patient, dose, route, dated and signed.

• Check allergies

• Wash hands with liquid soap and water

• Check all packaging for any damage and check the expiry dates prior to opening

• Using a blue needle and 10ml syringe draw up dose of iron and add to 250ml of 0.9% sodium chloride.

• Prime giving set with resultant solution.

• Complete IV additive label, checked and signed by 2 Registered Nurses

• Using tourniquet and cannula insertion pack, site venflon, secure with tape and flush with 5mls of 0.9% sodium chloride injection

• Attach primed volumetric giving set to venflon.

• Complete documentation.

• Entering information into volumetric pump give the infusion over at least 15 minutes.

Disconnecting the infusion

• Wash hands with liquid soap

• Apply alcohol hand rub to hands and rub until dry

• Disconnect giving set from venflon

• Remove venflon and apply pressure to puncture site using cotton wool

• Dispose of equipment correctly

• Record patient's blood pressure and pulse, Take appropriate action if abnormalities detected