

Renal Services

Intravenous (IV) Iron for Home Haemodialysis Patients

Background

Many People with kidney disease have a condition called anaemia. This is a lack of red blood cells in their blood stream. Red blood cells carry oxygen to muscles and other tissues. A lack of red blood cells can lead to symptoms such as tiredness, lethargy and breathlessness.

There are a number of factors which can cause anaemia in patients with kidney disease including low iron stores, bleeding, low levels of certain vitamins (Vitamin B12 and Folate) and a lack of a hormone called erythropoietin (or EPO).

Patients with low iron levels may often be given iron tablets in the first instance. Sometimes iron tablets are not well tolerated (They can cause gastrointestinal symptoms such as diarrhoea, constipation or abdominal pain) or do not adequately restore the body's iron levels. In these circumstances it is possible to give iron intravenously (directly into a vein via an injection or infusion, or directly into the dialysis machine).

What are the benefits?

The expected benefits of IV Iron are to help improve your anaemia, or prevent you from becoming anaemic. This may help improve or prevent the symptoms described above.



Are there any risks or side-effects?

Like all medicines, IV iron can cause side-effects although most people do not get any.

Common side-effects (less than 1 in 10 patients) include: headache, dizziness, hypertension, flushing, nausea, injection site reactions, low phosphate levels.

Uncommon side effects (less than 1 in 100) include: hypersensitivity, paraesthesia/numbness, increase in heart rate (tachycardia), hypotension, difficulty breathing, taste disturbance, vomiting, dyspepsia (heartburn), flatulence, abdominal pain, constipation, diarrhoea, itchiness, hives (Urticaria), redness (erythema), rash, muscle pain, muscle spasm, back pain, joint pain, pain in extremity, fever, fatigue, chest pain, accumulation of fluid in the periphery, pain and chills. Long lasting brown discolouration of the skin may occur due to leakage of the drug at the injection site.

The main risk of IV iron is a very rare but very severe risk of allergic hypersensitivity reactions. The medication will therefore usually be given in an environment where there are staff and equipment to provide resuscitation facilities (i.e. the dialysis unit or the Renal Day Case Unit). You will also be supervised for at least 30 minutes after receiving the IV iron. If you have ever suffered an allergic reaction to Iron **you must inform your doctor or nurse and must not receive IV iron.**

Iv Iron options for Home Haemodialysis Patients

Patients on in-centre Haemodialysis (HD) will usually receive IV Iron on a regular basis (for example weekly or monthly) and it will usually be given straight into the dialysis machine circuit. Patients not on HD (Peritoneal dialysis or not on dialysis) will usually be given the IV Iron as an infusion on the Renal Day Case Unit on Ward 50 at UHCW.

Patients on Home HD are given the choice of receiving IV Iron either on the Renal Day case Unit or administering it themselves at home. Although the risk of severe allergic reactions is no different in patients on Home HD, in context of a patient receiving a complex and theoretically risky home therapy such as haemodialysis it is felt that the risk of allergic reactions to IV Iron is likely to be comparable with the risk of complications of the dialysis itself. The decision to allow the option of IV Iron at Home was

Patient Information

taken after consultation with the Renal Association and is in line with the practice at other UK centres providing Home HD.

Your Home HD consultant will discuss the two options for IV Iron either at home or on the Renal Day Case unit. You will be given the original statement from the Medicines and Healthcare Products Regulatory Agency (MHRA) as well as the MRHA response to the Renal Association Clinical Vice-President. As the prescription of IV Iron for use at home is an off-licence prescription you will be asked to sign a consent form acknowledging these risks. At any point if you decide that the risk of IV Iron at home was not acceptable you will be offered IV Iron on the Renal Day Case Unit instead.

General Advice and Consent

Most of your questions may have been answered by this leaflet but remember that this is only the starting point for discussion with your healthcare team.

Before any doctor, nurse or therapist examines or treats you they must seek your consent or permission. In order to make a decision you need to have the information from health professionals about the treatment or investigation which is being offered to you. You should always ask them more questions if you do not understand or if you want more information.

The information you receive should be about your condition, the alternatives available to you and whether it carries any risks or benefits.

The Trust has access to interpreting and translation services. If you need this Information in another language or format please contact 02476863691 and we will do our best to meet your needs.

The Trust operates a smoke free policy

Document History

Department:	Renal
Contact:	02476863691
Updated:	December 2019
Review:	December 2021
Version:	1
Reference:	HIC/LFT/2401/19

Patient Information

Dear Home Haemodialysis patient,

You will probably have been aware that there has recently been a concern regarding the safety of intravenous (iv) Iron. The Medicines and Healthcare products Regulatory Agency (MHRA) sent out a Strengthened Recommendation on the use of iv Iron in August 2013. This recommendation is attached and can be found on their website at

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON300398>

This recommendation followed concern from France about hypersensitivity (allergic) reactions to iv Iron. The recommendation states that caution is needed with *every* dose of iv Iron, even when previous administrations (i.e. “test doses”) have been well tolerated. It also recommends that iv Iron products should only be administered when staff trained to evaluate and manage anaphylactic or anaphylactoid reactions—as well as resuscitation facilities—are immediately available.

It is because of this recommendation we withdrew the prescription of iv Iron (Venofer) to home haemodialysis (HD) patients.

Dr Graham Lipkin, Clinical Vice-President of the Renal Association has been in correspondence with the MHRA and received the attached reply. In summary, the MHRA remains clear in its guidance above but also states, “...a doctor may prescribe off-label if they consider that it is necessary, for medical reasons, in order to meet the specific needs of a patient and with the patient's informed consent.”

We have since been in discussion with a number of other renal centres with Home HD programmes. Many are planning to continue to offer patients iv Iron at home with patients' consent, on the basis that:

- The perceived risk is felt to be small
- The risk of allergic reactions to iv Iron is likely to be smaller than other risks associated with invasive treatments such as Home HD
- Many patients felt that the convenience of administering iv Iron at home justified this small increased risk

Patient Information

We are therefore willing to offer two options to patients on the Home HD programme at UHCW:

1. When necessary, attend the renal day unit at UHCW for an injection of Ferrinject.
 - This is a larger dose of iron than Venofer and would typically be required every 2-6 months.
2. Continue to self-administer Venofer at home.
 - This would be on the acceptance that:
 - The prescription is “off-label” and the risks stated above, whilst thought to be small, are recognised and real
 - You must have someone present during, and for 30 minutes after, the administration of the iv Iron

Consent

I have read and understood the above statement and would like to opt for Option
.....

Patient

Name

Signature

Date

Doctor

Name

Signature

Date