



Issue date

29 March 2023

Distributed to:

Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:

Chief Executives
Directors of Clinical Governance

We recommend you also inform:

Directors, Managers and Staff of:

- Pharmacy
- Medical Services
- Nursing and Midwifery
- Maternity Services
- Hospital in the Home and Ambulatory Care

Drug and Therapeutics Committees

Other relevant stakeholders including clinicians who may prescribe, dispense, and administer intravenous iron preparations

Expert Reference Group

Content reviewed by:

Medication Safety Expert Advisory Committee

Clinical Excellence Commission

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Review date

July 2024

Intravenous iron preparations and potential for skin staining

Situation

Skin staining is an uncommon but potentially permanent adverse effect of parenteral iron products that often follows extravasation into surrounding tissues (Figure 1).

Background

Iron deficiency is a common condition treated with oral and parenteral iron products. Use of parenteral iron therapy has increased in recent years, in part due to the availability of newer iron salts with favourable adverse effect profiles and shorter infusion times.

Skin staining is an uncommon adverse effect that can occur with intravenous infusions if there is clear extravasation into the surrounding tissues, but also in the absence of obvious extravasation. It has been reported with multiple iron preparations and doses. In some cases, skin staining is permanent and may have psychological implications for patients.

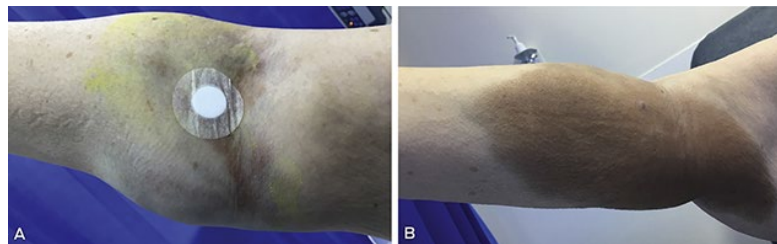


Figure 1. Image of skin staining with intravenous iron infusion.
Image adapted from Canning and Gilmore, 2017.

Signs and symptoms of extravasation include pain, burning, redness, swelling, feeling of pressure, irritation or prickling at the injection site and immediate observable staining of the surrounding tissue area.

The risk of skin staining associated with intravenous iron infusions can be reduced by adhering to clear administration and monitoring procedures and ensuring the appropriate training of staff and education of patients.

Clinical Recommendations

- To reduce the risk of skin staining, where appropriate, patients should be initially trialled on a course of oral therapy at an appropriate dose and duration.
- Patients must be educated on the possibility of permanent skin staining as part of the informed consent process, prior to receiving intravenous iron. This education should include adequate discussion regarding the risks and benefits of intravenous iron therapy and provision of written information (for example, [A general guide to iron and iron deficiency – Information for patients, families and carers](#)).

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- Prior to the administration of intravenous iron, patients should be advised to immediately notify clinical staff if any signs or symptoms of extravasation occur.
- All staff administering intravenous iron must be educated on local policies and procedures, be aware of monitoring requirements and the signs and symptoms of potential adverse effects.

When intravenous iron therapies are clinically indicated, clinicians should employ infusion techniques to minimise the risk of staining, including:

- Insert an appropriate gauge peripheral cannula (20- to 24- gauge) via the distal veins of the forearm (preferred site). Cannulation at sites of flexion or on the back of the hand should be avoided (where possible).
- Ensure the cannula is secure and that an extension set is used to minimise cannula movement (avoid covering the site with a bandage that prevents visual inspection).
- Ensure that the patency of the vein is established with a flush prior to administration.
- Ensure the infusion duration is in accordance with the Product Information.
- Regular monitoring of the cannula site should be timed to correspond with the collection of other vital signs in accordance with local protocols for infusion.

The risk of extravasation is increased if multiple venepunctures occur during attempts at cannulation. For patients who are difficult to cannulate or in the event of multiple attempts at cannulation, consider postponing the administration of intravenous iron therapy.

There are currently no published guidelines outlining how to manage iron extravasation or skin discolouration. If extravasation occurs during administration, the infusion should be ceased immediately, and the site assessed. Clinicians should disconnect the giving set, aspirate any residual drug from the cannula and remove the cannula. A cold pack may be applied to prevent swelling or soreness.

Clinicians should seek expert guidance on the management of skin staining. Laser therapy can be considered as a treatment.

References

1. Canning M, Grannell L. A stain on iron therapy. *Aust Prescr* 2020;43:160-3. Available from DOI: 10.18773/austprescr.2020.051
2. Canning M, Gilmore K. Iron stain following an intravenous iron infusion. *Med J Aust* 2017;207:58.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant clinicians, clinical departments where intravenous iron is prescribed, dispensed and administered, and include this Safety Information in relevant handovers and safety huddles.
2. Report any incidents associated with intravenous iron administration and skin staining into the local incident management system (e.g., [ims+](#)) and [TGA](#).