Ferric carboxymaltose: A practical guide on the administration of iron infusions in general practice

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Background
Despite having strong knowledge on iron deficiency, there is ongoing hesitancy among general practitioners (GPs) in providing iron infusions due to reduced confidence in the administration technique and concerns about adverse events.

Objective
This article aims to prepare GPs, general practice registrars and other health providers with the knowledge to confidently and safely perform ferric carboxymaltose (FCM) infusions. It provides education around the use of parenteral iron, including indications, storage, administration, PBS (Pharmaceutical Benefits Scheme) subsidy, side effects, contraindications and benefits. It might also assist already seasoned GPs with supplementary information, or those not performing infusions, with information about pre- and post-infusion care.

Discussion
GPs play a pivotal role in both detection and management of iron deficiency and are arguably best suited to facilitate iron infusions. The goal is to reduce the responsibility burden on the hospital system, as well as assist GPs to maintain advanced skills and provide holistic care.

IRON INFUSIONS have become increasingly popular as a general practitioner (GP)-led treatment for iron deficiency and iron deficiency anaemia (IDA).[1–3] This has been particularly noted since the introduction of ferric carboxymaltose (FCM) to the Pharmaceutical Benefits Scheme (PBS) in 2014 and the unexpectedly rapid uptake of its use by Australian GPs.[3,4] In addition to this, the latest intravenous (IV) formulations are argued to have an improved safety profile.[5,6]

Occasionally, oral supplementation is not appropriate due to its: (1) slower correction of iron deficiency in comparison to its IV counterparts; (2) reduced efficacy because of impaired intestinal absorption; or (3) non-compliance rates due to side effects.[1–3,5,7] In addition, intramuscular (IM) preparations such as iron polymaltose (Ferrosig, Melbourne, Vic, Australia) tend to be less favoured due to their administration technique and dermatological complaints (eg scarring and iron stain reactions).[3,4] Therefore, IV infusions are gaining popularity as an alternative to both oral and IM formulations.

PBS-subsidised parenteral preparations and indications

IV preparations in Australia listed on the PBS include FCM (Ferinject, Melbourne, Vic, Australia), ferric polymaltose (Ferrum H [Melbourne, Vic, Australia], Ferrosig), ferric derisomaltose (Monofer, Sydney, NSW, Australia) and iron sucrose (Venofer, Melbourne, Vic, Australia).[2,4]

Iron polymaltose and sucrose might be preferred for hospital inpatients due to their PBS restrictions and longer administration times.[2] Iron polymaltose is PBS listed for use in patients with enteric concerns (eg malabsorption and gastrointestinal side effects), whereas iron sucrose is listed for use in patients receiving haemodialysis and supplemental erythropoietin therapy.

FCM tends to be favoured in community settings due to its availability, ease of administration and efficacy with reduced doses.[2,4] It is registered for use for IDA in children aged 1–13 years and iron deficiency in those aged >14 years.[1,2] For PBS subsidy, the diagnosis must be confirmed on laboratory testing and oral iron must not a reasonable substitute.

A suitable alternative to FCM in a GP setting is iron derisomaltose (Monofer). Although iron derisomaltose is argued to have a lower risk of hypophosphataemia, the overall side effect profile is argued to be higher.[8] The choice to use derisomaltose versus FCM might vary based on practitioner experience, practice policy and availability.

Ferric carboxymaltose (Ferinject)

FCM is a colloidal solution stabilised by a carbohydrate complex that allows the controlled delivery of iron to storage sites.[5–7] It can be used as an injection, infusion or in

haemodialysis, as listed in Table 1.[1,2] It is available in 2 mL × 100 mg (for dilution in 0.9% saline), 10 mL × 500 mg (prediluted, PBS subsidised and preferred) and 20 mL × 1000 mg vials (prediluted).[1] It is stored at room temperature; refrigeration, freezing and storage above 30°C is not advised; however, it can be used if refrigerated between 2°C and 8°C for <12 hours.[2] It should be used directly after opening.[1]

Laboratory indications for parenteral infusion

Although the decision to proceed with an infusion varies based on practitioner preference and the medical condition being addressed, the general consensus is that it is indicated when the serum ferritin is below the laboratory reference range (RR) and oral iron is not a reasonable alternative. Specifically, a serum ferritin of <30 ng/mL has a high sensitivity and specificity for iron deficiency, but most laboratories will use a lower cut-off range of 15–25 ng/mL.

It is important to note that this RR is adjusted when an inflammatory process is present (ie C-reactive protein [CRP] above 5 mg/L) or in certain medical conditions (eg chronic kidney disease [CKD] and symptomatic congestive heart failure) with a concurrent reduced transferrin saturation (of <16–20%). In these cases, ferritin is considered low if below 100 ng/mL.

Iron deficiency anaemia, regardless of severity, is also an indication for infusion. If an anaemia is present (ie haemoglobin [Hb] <13 g/dL in men and <12 g/dL in non-pregnant women), it suggests the iron deficiency is advanced and requires infusion.[9]

Benefits

FCM has shown to be beneficial in the treatment of chronic heart failure,[10] perinatal IDA,[4,7,10] heavy uterine bleeding,[7] inflammatory bowel disease (IBD),[4,10] upper gastrointestinal bleeding,[9] CKD,[7,10] malignancy[10] and perioperative anaemia[4,7] (among others). It is generally well tolerated with a low risk of hypersensitivity and gastrointestinal side effects.[7,10] Oxidative stress reactions, as seen in those with hyperferritinaemia, are also low risk.[7] It is also cost effective in comparison to oral formulations as fewer doses are required for the desired effect.[7,10]

Supporting studies show that FCM is comparable to oral ferrous sulphate and superior to iron sucrose in both improving Hb, ferritin, transferrin saturation levels and compliance rates in various patient groups.[2,7] It is also rapid; up to 99% iron utilisation within 6–24 days[2,7] and a Hb rise of 20–30 g/L within eight weeks[11] post-transfusion has been demonstrated in some studies. It was also seen to normalise platelet counts in those with IBD within six weeks.[7]

Contraindications

Absolute contraindications for the use of FCM include:

- Age <1 year[1]
- Hyperferritinaemia[1–3]
- Known allergy to ingredients[1–3]
- Anaemia of another cause[1–3]
- Some medical conditions including severe asthma, severe liver or renal inflammation, uncontrolled hyperparathyroidism, chronic polyarthritis and Ostler–Rendu–Weber syndrome.[3,12]

Relative contraindications

Relative contraindications for the use of FCM include:

- Pregnancy: There is no safety data before 16 weeks' gestation.[1,2,12] The risk includes maternal allergy leading to slowed foetal

Table 1. Ferinject administration using various methods[1,2,13]

Weight-based calculation

Product information	Ganzoni method	Simplified method
Undiluted infusion Over 15 min Patients aged 1–13 years: 750 mg (15 mL) – avoid use where possible[14] Patients aged >14 years: 1000 mg (20 mL)	Iron dose (mg) = (bodyweight [kg] × [target Hb below – actual Hb] × 0.24] + iron depot *>34 kg bodyweight:* Target Hb = 150 g/L Iron depot = 500 mg *≤34 kg bodyweight:* Target Hb = 130 g/L Iron depot = 15 mg/kg	*Weight >70 kg* 1500 mg if Hb >100 g/L 2000 mg if Hb <100 g/L *Weight 35–70 kg* 1000 mg if Hb >100 g/L 1500 mg if Hb <100 g/L
Diluted infusion As above, diluted in 250 mL normal saline		
Haemodialysis (patients aged >14 years) Maximum 200 mg (4 mL) over 10–15 min		

Notes:

- Providers must check relevant state and national guidelines prior to using the above dosing recommendations.
- Doses >1000 mg require divided doses at least 7 days apart with a maximum dose of 20 mg/kg per administration.[2,7,12]
- For patients with a Hb level >140 g/L, a dose of 500 mg is recommended irrespective of weight.[15]
- The Ganzoni method is useful for pregnant, elderly and paediatric populations and those with a Hb level <70 g/L.

Hb, haemoglobin.

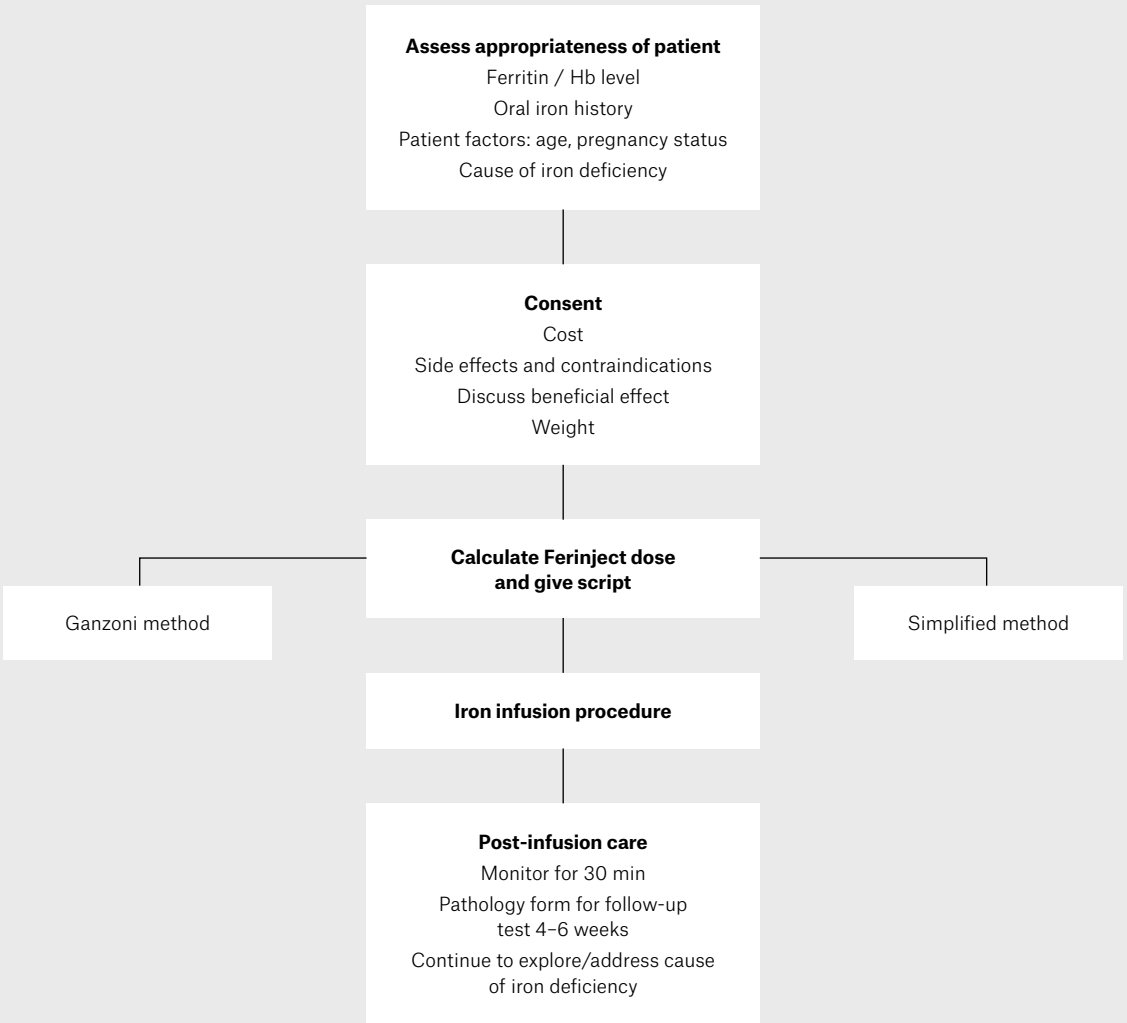

Figure 1. Summarised steps to conducting a ferric carboxymaltose infusion.
Hb, haemoglobin.

heart rate (HR),[1,2] although this has been argued to be negligible.[7] Use with caution and use oral iron where preferable.

- Infection: FCM might worsen pre-existing infection.[1]
- Liver abnormalities: Given the liver is an iron storage site, GPs need to carefully monitor iron status and titrate doses to avoid iron overload.[1]

Iron infusion procedure

A summary of the FCM infusion procedure is outlined in Figure 1.

Pre-infusion consultation

A pre-infusion consultation is recommended to ensure that all aspects of the infusion are addressed prior to the procedure date.[13] Pathology (ie Hb, iron studies ± CRP) should be obtained to confirm infusion suitability, PBS eligibility and assist with dose calculation.[1,13] The GP should also explore causes of iron deficiency and whether further testing (eg coeliac screen, vitamin D level, B12/folate level, liver function tests, thyroid function tests or endoscopy) or specialist referral (gynaecologist, nephrologist or haematologist) are required.[13] The patient should complete a signed consent following discussion about the procedure and follow-up, contraindications, allergies and side effects.[13,14] In particular, patients must be explicitly informed about the risk of iron extravasation and provide consent; this must be clearly documented due to its high medico-legal risk.

The patient's weight should be obtained for accurate dose calculation, as per the information provided in Table 1, prior to providing a FCM script.[14] Patients can then be advised to collect the ampoules from the pharmacy prior to the procedure and store

them at room temperature. It is important to note a maximum dose of 20 mg/kg of body weight and 1000 mg per iron administration; split dosing with a minimum interval of seven days is recommended for doses higher than this 1000 mg.[2,8,1] According to the New Zealand Medsafe guidelines, in patients with a Hb >140 g/L, a lower dose of 500 mg is recommended irrespective of weight.[15]

FCM administration

Examples of the equipment set up and utilisation can be seen in Figures 2 and 3. The GP might find it beneficial to have a trained nurse assist with observations and equipment set up. In addition to this, full cardiopulmonary equipment should be available and staff training should be completed in the event of an anaphylaxis.[12] A trained practitioner (GP or nurse) is recommended to personally administer and oversee the iron infusion to limit adverse effects (eg iron extravasation). They might also wish to personally inspect the FCM vial for sediment and check the expiry date before use.[12]

The cannula should ideally be inserted into the distal upper limb with avoidance of flexure sites (eg cubital fossa) to reduce risk of paravenous leakage.[6,13,14] This might not always be possible, as demonstrated in Figure 3. If multiple cannula attempts are required, it is advised to change the arm being used.[12]

The FCM infusion is administered as per the dose calculations in Table 1. It is recommended to start with a slow infusion rate.[6] A 10 mL saline flush is recommended prior to and after the iron infusion to reduce skin reactions.[2,12,13] Regular observations (temperature, blood pressure [BP], heart rate [HR], saturations) are recommended at least prior to, during and after the infusion.[12–14]

Following the infusion, the patient should be observed for 30 minutes in the event of a delayed reaction (usually hypertension and hypersensitivity).[2,12,13] Patients should be advised to notify staff of any chest tightness, dyspnoea, tachycardia, itch or nausea.[12] At 30 minutes post infusion, observations should be rechecked.[12]

Although not likely harmful, oral iron after infusion is not necessary and concurrent use with FCM reduces the efficacy of oral iron.[1,13]

Figure 2. Suggested equipment set up for ferric carboxymaltose infusion via slow push in a general practice setting.

Pathology follow-up

The patient should ideally have follow-up pathology (eg Hb, ferritin) after 4–6 weeks to determine the efficacy of the infusion and record an initial measurement; checking prior to this time might cause misleading results.[7,13] On most occasions, the ferritin and/or Hb will normalise and patients will report symptomatic relief.[7,13] Less commonly, an overcorrection of ferritin might require monitoring.[1] Conversely, an inadequate response might occur, highlighting a need to reassess the cause of the iron deficiency and persistent iron loss.[12]

In addition, the GP might wish to monitor phosphate levels in patients with symptomatic hypophosphataemia (as described in Table 2) or pre-emptively offer a pathology form.[16] However, it is argued that this might lead to unnecessary intervention and could be limited to patients with moderate to severe symptoms.[17] Low vitamin D levels, raised alkaline phosphatase (ALP) or raised parathyroid hormone (PTH) might also be noted in symptomatic patients.[1,5,17]

The GP should recheck levels again after 2–3 months (if the patient had a good initial response and significant blood loss is not anticipated); this might be repeated until iron levels are stable.[13] Patients might also require ongoing infusions to maintain levels, which might once again prompt the need to reassess the cause of the iron deficiency. In this situation, they should be educated on the risk of hypophosphataemia with repeated infusions.

Managing side effects

The expected side effects to FCM infusions are summarised in Table 2. Data available include documented side effects up to 24 weeks, post infusion.[2] Most reactions were transient and mild and lasting between one and two days, with onset estimated within two days.[3]

Hypophosphataemia

Hypophosphataemia is the most common side effect of FCM infusions in comparison to other parenteral formulations.[5,7,16] It is defined by a serum phosphate of <0.65 mmol/L or 2 mg/dL.[5] Patients at risk include those who have had high or repeated doses (eg two or more infusions within six months),[3,5,12,16] as well as those

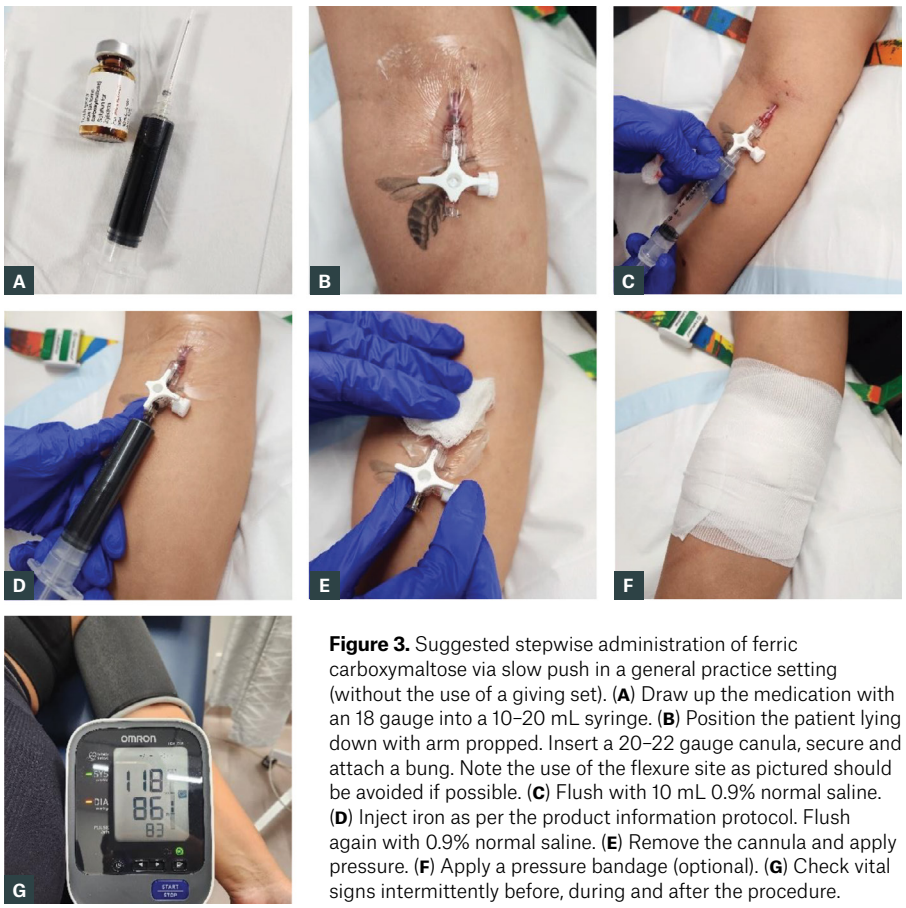

Figure 3. Suggested stepwise administration of ferric carboxymaltose via slow push in a general practice setting (without the use of a giving set). (**A**) Draw up the medication with an 18 gauge into a 10–20 mL syringe. (**B**) Position the patient lying down with arm propped. Insert a 20–22 gauge canula, secure and attach a bung. Note the use of the flexure site as pictured should be avoided if possible. (**C**) Flush with 10 mL 0.9% normal saline. (**D**) Inject iron as per the product information protocol. Flush again with 0.9% normal saline. (**E**) Remove the cannula and apply pressure. (**F**) Apply a pressure bandage (optional). (**G**) Check vital signs intermittently before, during and after the procedure.

with low BMI, reduced nutritional status, low basal phosphate, severe iron deficiency and chronic diarrhoea.[12,16] Patients are usually asymptomatic, but might rarely present with fatigue or persistent arthralgia and bone thinning (hypophosphataemic osteomalacia).[2,6,17]

The effects of hypophosphataemia might last up to 80–180 days post infusion.[11,17] In addition, low vitamin D, raised ALP or raised PTH might persist for longer.[16] The cause is unclear, although it is thought to be due to an increased intact fibroblast growth factor 23 (iFGF23),[7,11,16–19] leading to secondary hyperparathyroidism (low calcitriol, calcium, phosphate and high PTH) and is associated with an increase in urinary phosphate excretion.[17]

As seen in Table 2, oral or IV supplementation of phosphate might be required depending on severity. The use of supplemental vitamin D is still contentious; prior monitoring or supplementation might be considered,[16] but is argued to not be clearly beneficial.[17] Persistent arthralgia might require an X-ray or bone scan.[17] It is advised to consider using alternate parenteral iron formulations in high-risk patients.[15]

Hypersensitivity reactions and anaphylaxis

Hypersensitivity reactions might be present as an immediate or delayed reaction. For mild reactions, patients might report dyspnoea, tachycardia, sweating, flushing, nausea and chest pain, which might last up to seven days.[11] If onset is during the infusion, the infusion should be paused and recommenced at a slower rate if symptoms improve.[6,7] Antihistamine and/or corticosteroids use under close observation might be indicated.[6,11]

The incidence of severe hypersensitivity reactions, such as anaphylaxis to iron sucrose, ferric derisomaltose and ferric carboxymaltose, are rare (<2%).[2,5,7,11] Signs might include wheeze, stridor, periorbital oedema, cyanosis, syncope and cardiac arrest.[12] The practice must be equipped with full cardiopulmonary equipment and have provided appropriate staff training, and a standard adrenaline administration protocol should be followed.[12] Patients must be educated to present to hospital in the event of lightheadedness, breathing difficulty and perioral or neck swelling hours to days after the infusion.

The Canadian expert consensus guidelines recommend changing iron formulation or slowing the rate of infusion when re-challenging those with previous hypersensitivity reactions.[20] There are supporting retrospective studies to show success with this technique, with some being successfully rechallenged with the same parenteral iron.[6,12] For safety reasons, the author recommends rechallenging these patients in a controlled setting (ie hospital setting).

Iron staining

An iron stain is a permanent tan-coloured stain due to the extravasation of iron products at the injection site.[7,13] It is the most common cause of iron infusion-related litigation[1,5] and should be emphasised when obtaining consent for the infusion. Avoidance of flexural sites for cannulation (such as the cubital fossa), ensuring patency of the cannula prior to the infusion, and close monitoring for extravasation during the infusion might mitigate this risk.[6]

If pain, swelling or discolouration occurs, the practitioner should immediately cease the infusion and apply a cold compress.[7,13] They should avoid bandage use.[12,13] Significant reactions might necessitate the use of hydrocortisone 1% cream or referral to plastic surgery.[12] The author suggests seeking medical indemnity advice in this scenario.

Conclusion

The benefit of performing iron infusions likely outweighs the perceived risk of adverse effects. Benefits include providing holistic and convenient patient care, rapid improvement in Hb and ferritin levels, advancing GP skill sets and reducing hospital burden. Despite this, GPs should have

Table 2. Side effects noted up to 24 weeks following iron infusions including FCM

Reaction	Frequency	Description	Management
Hypophosphataemia	1.9–92%[2,6,11,16,17]	• Serum phosphate 0.65 mmol/L or <2 mg/dL • Often asymptomatic in up to 75% of patients;[16] rare fatigue, weakness, nausea, diarrhoea, persistent arthralgia or bone thinning (hypophosphataemic osteomalacia)[2,6,17] • Lasts up to 80–180 days post iron infusion[11,17] • Common with FCM, especially in high or repeated doses (≥2 infusions within 6 months),[3,5,12,16] low BMI or nutrition, low basal phosphate, severe iron deficiency and chronic diarrhoea[12,16] • Cause unclear; it is thought to be due to increased intact fibroblast growth factor 23 (iFGF23),[7,11,16–19] leading to secondary hyperparathyroidism and increased urinary phosphate excretion[17]	Consider alternate parenteral iron in high-risk patients[16] **Phosphate supplementation:** *Mild to moderate:*[22] • Observe and retest • High phosphate diet[23] • Phosphate sandos 1–2 tablets up to 3 times a day and weekly blood monitoring • If not tolerating, IV administration 10 mmol sodium dihydrogen phosphate in 250 mL normal saline 0.9% over 2–6 h and monitor calcium, phosphate, renal function every 12–24 h *Severe <0.4 mmol/L*: Emergency referral for IV – might require rapid or regular infusions[16,22] Persistent arthralgia might require an X-ray or bone scan[17] *Vitamin D supplementation*: Prior Vitamin D monitoring or supplementation might be considered,[16] but is argued to not be clearly beneficial[17]
Hypersensitivity/ Mild–moderate allergy	0.2–1.7%[2,5,7,11]	• Dyspnoea, lightheadedness, tachycardia, sweating, nausea, flushing, urticaria, limb tingling or swelling, metallic taste, headache and chest pain up to 7 days[12]	• Pause or slow the infusion and recommence at a slower rate after 15 min if symptoms improve[6,7,11] • Antihistamine and/or corticosteroids might be indicated[6,11] • Paracetamol and NSAIDs are alternative options[12]
Anaphylaxis	<1%[2,7,11]	• Wheeze, stridor, periorbital oedema, cyanosis, syncope and cardiac arrest[12]	• Full cardiopulmonary equipment and staff training should be available.[2,12] Anaphylaxis management includes the adrenaline administration protocol[12] • Patients must be educated to present to hospital if delayed symptoms appear within days after infusion. Avoid further use of iron product if anaphylaxis occurs[13]
Hypertension/ hypotension	1.3%[2]	• Hypertension is dose-dependent.[2,13] It is most commonly observed in the waiting period[2]	Slowing the infusion is recommended[6,13]
Skin reactions	1.6–2.1%[2,5]	*Iron stain and other skin reactions (swelling, rash)* • A permanent tan-coloured stain due to paravenous leakage at the injection site[7,13] • High risk for iron infusion-related litigation[1,5]	• Avoid flexural cannulation sites, ensure patency of cannula prior to infusing and closely monitor for extravasation[6] • If pain, swelling or discolouration occurs, immediately cease and apply cold compress.[7,13] Consider hydrocortisone 1% cream.[12] Avoid bandage use.[12,13] • Consider plastic surgery referral for washout if significant[12] • The author suggests seeking medical indemnity advice in this scenario

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Table 2. Side effects noted up to 24 weeks following iron infusions including FCM (cont'd)

Others		
Tachycardia	Lightheadedness (1.2%[2])/syncope	Myalgia/muscle spasm
Fever	Headache (1.4%[2])	Flu-like illness
Chest pain	Pallor	Taste disturbance
Gastrointestinal upset: nausea (3.1%[2]), constipation, diarrhoea, abdominal discomfort, reflux, bloating	Deranged LFTs: Increased aspartate aminotransferase, gamma-glutamyltransferase, blood lactate dehydrogenase and blood alkaline phosphatase[1,2]	

BMI, body mass index; FCM, ferric carboxymaltose; IV, intravenous; LFTs, liver function tests; NSAIDs, non-steroidal anti-inflammatory drugs.

prior awareness to the risks, side effects and contraindications associated with this procedure to enable them to confidently and competently administer FCM.

Further learning

The author suggests to using the various online learning modules and applications available when commencing iron infusions. Resource examples include the National Prescribing Service (NPS),[1,2] National Blood Authority of Australia,[21] BloodSafe eLearning Australia[13] and the relevant state Health Pathways.

Key points

- There has been an increase in the uptake of parenteral iron administration in recent years.
- Iron infusions can be considered when there are concerns about non-compliance or poor absorption with oral iron, or when rapid correction of Hb and ferritin levels is necessary.
- Ferric carboxymaltose (Ferinject) has become an increasingly popular option in a GP setting because of a favourable side effect profile and PBS subsidies.
- It is not recommended to exceed a FCM dose of 1000 mg or 20 mg/kg of body weight per infusion administration. If higher doses are required, split dosing with a minimal interval of seven days is recommended.
- Hypophosphataemia is the most common side effect of FCM and might require oral or IV phosphate supplementation.
- Iron extravasation leading to skin staining is the adverse effect with the highest litigation risk.

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