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IRON POLYMALTOSE INFUSIONS DISCUSSION PAPER

Rapid Response to Iron Polymaltose Infusions Email Discussion

NSW THERAPEUTIC ADVISORY GROUP
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Email Discussion Question: (circulated November 14, 2008)

Based on discussions at the NSW TAG General Committee meeting held on the 27th October 2008 RNSH has asked the following: We are currently considering an Area policy for the administration of IV infusion of iron polymaltose (Ferrosig) and are interested in what is current policy (or practice) across the NSW TAG network. Would members be willing to provide a copy of their current policy/protocol/practice regarding iron polymaltose infusions?

NSW TAG received 14 policies in response to this question. Details of policies submitted are available in the members section of the NSW TAG website (a user name and pass word are required). The overall approach to managing iron polymaltose infusions is generally similar across the policies received, with some minor differences noted (Table 1).

The following summarises the institution-based recommendations/guidelines for managing iron polymaltose infusions:

- 12 policies start with a test dose which is then titrated upwards to a maximum infusion rate of 120 mL/h. This is consistent with recommendations in the product information.^{1,2} One policy allows for a maximum infusion rate of 180 mL/h. One policy allows for a maximum infusion rate of 60 mL/h
- 10 policies require the iron polymaltose to be diluted into 500 mL normal saline. Two policies allow for varying volumes of normal saline dependent on total prescribed iron dose. A further policy allows for variation in normal saline volume dependant on age of patient or presence of heart failure. One policy does not specify the infusion volume.
- 11 policies require a maximum iron concentration of 5 mg/mL regardless of volume of normal saline. In 3 policies it is unclear what the maximum concentration of iron should be.
- All policies define vital sign monitoring requirements, but requirements are generally different at each institution
- Three policies require premedication with antihistamine and or corticosteroids. A further allows for premedication at the discretion of the treating doctor.
- Six policies require resuscitation equipment to be available.

We requested information from the Adverse Drug Reaction Advisory Committee regarding reported adverse events with iron polymaltose infusions. As at October 2008, there had been 229 reported adverse drug reactions associated with iron polymaltose infusions. This data can be difficult to interpret because of its voluntary and therefore incomplete nature. With this limitation in mind, the data shows of the 229 reported cases:

- 1 patient died
- 18 patients were recorded as having a severe or life threatening reaction
- 29 patients were recorded as requiring further medical consultation or prolonged hospitalisation
- 11 patients were admitted to hospital following the infusion
- 59 patients were recorded as having the infusion ceased
- 105 patients were recorded as requiring additional medication, fluids or oxygen

¹ Ferrosig (Iron Polymaltose Complex) Injection Product Information: Sigma Pharmaceuticals (Australia) Pty Ltd. Available at MIMS Online <http://mims.hcn.net.au>

² Ferrum H (Iron Polymaltose Complex) Injection Product Information: Aspen Pharmacare Australia Pty Ltd. Available at MIMS Online <http://mims.hcn.net.au>

Table 1: Summary of policies received by NSW TAG

Facility	Date of policy	Initial infusion rate	Max infusion rate	Saline volume	Max []	Vital sign monitoring requirements	Other instructions	Resuscitation equipment should be available	Who for	instruction given for dialysis patients
1	July 2008	20-40mL/h for 1h and 15 min	120 mL/hour	500 mL	5mg/mL	Baseline, 15 minutely for 1 hour, then every 30 minutes till 30 minutes post infusion		Not specified	Iron Deficiency Anaemia (IDA)	N
2	February 2008	40 mL/h for 1 h and 15 min	120 mL/h hour over 3h & 45 min	500 mL	5mg/mL	Baseline, 15 minutely for 30 minutes, then hourly till 1 hour post infusion	Premedication if history of allergies	Y	Not specified	N
3	October 2008	50 mL/h	120-180 mL/h in no less than 3 hours	500 mL	Not clear	Every 5 min for 15 minutes, then every 15 minutes for 45 min, then hourly till infusion completion, then 30 minutes post infusion		Not specified	IDA	Y
4	August 2007	10 mL/h for 30 min	If no problems then remainder of infusion over 1h – total infusion over 90 min	500 mL unless >80 yrs or CCF then 100 mL	Not clear could be up to 24.5 mg/L	At 15 and 30 min	Premedication antihistamine / corticosteroid	Not specified	IDA /perioperative	Y
5	December 2006	30 mL/h for 10 minutes	Incremental increases up to 125 mL/h (150 mL/h for dialysis patients)	500 mL	5mg/mL	Baseline, then at 5 min, then every 30 min for 1h, then hourly till infusion completion, then 30 min post infusion		Not specified	Patients with IDA unable to tolerate oral therapy / dialysis	Y
6	Not specified	10 mL/h for 1h	120 mL/h – as fast as 2 hours if patient remains symptom free	250 mL	5mg/mL	Every 5 min for 30 min, then every 15 min for 1h, then every 30 min till infusion complete	Continuous ECG and SaO2 monitoring	Not specified	Not specified	N
7	February 2006	20-40 mL/h for 1h and 15 min	120 mL/h – total infusion time = 5h	500 mL	5mg/mL	Every 5 min for 15 min, every 15 min for 1h then hourly till infusion complete		Not specified	IDA / End Stage Renal failure (ESRF)	N

Facility	Date of policy	Initial infusion rate	Max infusion rate	Saline volume	Max []	Vital sign monitoring requirements	Other instructions	Resuscitation equipment should be available	Who for	instruction given for dialysis patients
8	March 2007	30 mL/h for 1h and 40 min	120 mL/h	250 mL / 500 mL depending on prescribed dose	5mg/mL	Baseline then every 5 min for 30 min, then every 30 min till infusion complete (more frequently if required)		Y	Not specified	N – separate guideline
9	February 2007	15 mL/h for 30 min	120 mL/h	500 mL	5mg/mL	Every 15 min for 30 min then hourly till infusion complete		Y	IDA	N
10	January 2007	40 mL/h for 15 min	Titrated up to 120 mL/hr as per protocol	500 mL	5mg/mL	Every 15 min for 1h, then hourly till discharge		Y	IDA	N
11	Not specified	18 mL/h for 10 min	Titrated up to 120 mL/h as per protocol	500 mL	5mg/mL	Every 10 min for 1h, then every 30 min till infusion complete		Not specified	Not specified	N
12	April 2008	20 mL/h for 10 min	Titrated up to 125 mL/h as per protocol	500 mL	5mg/mL	Baseline then every 10 min for 1h, then every 30 min till infusion complete and 1h post infusion	Premedication with paracetamol / antihistamine / hydrocortisone	Y	IDA	N
13	July 2008	40 mL/h for 75 min	120 mL/h	Variable depending on iron dose	5mg/mL	Baseline, then every 15 min for 1h, then hourly till completion of infusion	Direct nursing supervision for 1 st 15 min	Y	IDA / perioperative	N – separate guideline
14	2006	30 mL/h for 1 h	60 mL/h	Not specified	Not specified	Baseline then every 15 min for 30 min, then hourly till infusion complete and 1h post infusion	Premedication at discretion of treating doctor	Not specified	Not specified	N