New Drug

ferumoxytol

An intravenous iron, riskier than iron sucrose

Pharmacovigilance data and the results of a clinical trial show that serious adverse events are more frequent with ferumoxytol than with iron sucrose.

In patients with chronic renal failure, iron sucrose is the standard treatment for iron-deficiency anaemia when the intravenous route is preferable to the oral route (1-3). IV iron polymaltose has no clinical advantages, and IV iron dextran carries too high a risk of severe hypersensitivity reactions.

Ferumoxytol (Rienso® Takeda), another intravenous iron product, has been authorised for use in this setting. It is a colloidal complex of iron and sugar dextran, also known as polyglucose sorbitol carboxymethyl ether (3). Does it have any advantages over IV iron sucrose?

A trial versus IV iron sucrose. According to reports issued by the European and US drug regulatory agencies, clinical evaluation of IV ferumoxytol is based on three randomised, unblinded trials versus oral iron in 837 patients with chronic renal failure, not all of whom were on haemodialysis (3,4).

A randomised, unblinded trial comparing IV ferumoxytol with IV iron sucrose in 605 patients in whom oral iron had failed showed no difference between the groups in terms of the increase in haemoglobin during the 5 weeks of treatment (5).

More serious adverse effects. In the three trials versus oral iron, the adverse effect profile of IV ferumoxytol was similar to that of other IV iron products, and included cutaneous disorders, gastrointestinal disorders, fever, muscle and joint pain, and hypersensitivity reactions (a)(3,4).

In the unblinded trial versus IV iron sucrose, adverse effects were similarly frequent with the 2 products, but severe adverse effects occurred in 4.2% of patients treated with ferumoxytol versus 2.5% of those receiving iron sucrose (5).

A US pharmacovigilance review of different IV iron products examined adverse effects reported between October 2009 and June 2010 (6). The frequency of fatal, severe or serious adverse reactions per million units sold was significantly higher with ferumoxytol than with iron sucrose and with another iron dextran product.

Pregnancy. Animal studies of ferumoxytol have shown reproductive toxicity; this drug should therefore be avoided during pregnancy (7).

Convenience. Iron sucrose is infused slowly, after dilution, while ferumoxytol is injected rapidly, without dilution. In dialysis patients, ferumoxytol is injected directly into the dialysis line, as is iron sucrose.

In practice: do not use. In patients requiring intravenous iron administration, there is no firm evidence that ferumoxytol is more effective than iron sucrose, while it appears to have more serious adverse effects. It is better to avoid using ferumoxytol and to choose iron sucrose instead.

ferumoxytol

Rienso®

Solution for IV injection

• 510 mg of iron (ferumoxytol) per 17-ml vial (30 mg/ml)

antianaemic

Indication: "(…) iron deficiency anaemia in adult patients with chronic kidney disease (…)".

[EU marketing authorisation, centralised procedure]