



Evaluation of published clinical and non-clinical studies with different i.v. iron products in this review suggests that study results obtained with one i.v. iron product should not be assumed to be equivalent to other i.v. iron products that lack comparable study data in CHF” Martin-Malo et al (2019).

Abstract:

Iron deficiency is the leading cause of anaemia and is highly prevalent in patients with chronic heart failure (CHF). Iron deficiency, with or without anaemia, can be corrected with intravenous (i.v.) iron therapy. In heart failure patients, iron status screening, diagnosis, and treatment of iron deficiency with ferric carboxymaltose are recommended by the 2016 European Society of Cardiology guidelines, based on results of two randomized controlled trials in CHF patients with iron deficiency. All i.v. iron complexes consist of a polynuclear Fe(III)-oxyhydroxide/oxide core that is stabilized with a compound-specific carbohydrate, which strongly influences their physico-chemical properties (e.g. molecular weight distribution, complex stability, and labile iron content). Thus, the carbohydrate determines the metabolic fate of the complex, affecting its pharmacokinetic/pharmacodynamic profile and interactions with the innate immune system. Accordingly, i.v. iron products belong to the new class of non-biological complex drugs for which regulatory authorities recognized the need for more detailed characterization by orthogonal methods, particularly when assessing generic/follow-on products. Evaluation of published clinical and non-clinical studies with

different i.v. iron products in this review suggests that study results obtained with one i.v. iron product should not be assumed to be equivalent to other i.v. iron products that lack comparable study data in CHF. Without head-to-head clinical studies proving the therapeutic equivalence of other i.v. iron products with ferric carboxymaltose, in the highly vulnerable population of heart failure patients, extrapolation of results and substitution with a different i.v. iron product is not recommended.

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Reference:

Martin-Malo, A., Borchard, G., Flühmann, B., Mori, C., Silverberg, D. and Jankowska, E.A. (2019) Differences between intravenous iron products: focus on treatment of iron deficiency in chronic heart failure patients. ESC Heart Failure. January 29th. .

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