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Correction to: Intravenous Ferric Carboxymaltose in Patients with Type 2 Diabetes Mellitus and Iron Deficiency: CLEVER Trial Study Design and Protocol

Schindler, Christoph ; Birkenfeld, Andreas L ; Hanefeld, Markolf ; Schatz, Ulrike ; Köhler, Carsta ; Grüneberg, Martin ; Tschöpe, Diethelm ; Blüher, Matthias ; Hasslacher, Christoph ; Bornstein, Stefan R

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CORRECTION

Correction to: Intravenous Ferric Carboxymaltose in Patients with Type 2 Diabetes Mellitus and Iron Deficiency: CLEVER Trial Study Design and Protocol

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In the original publication, the text in Table 2 stated ‘Hypersensitivity to the active substance, to Ferinject, or to any of its excipients’. The authors would like to make changes to the text and have replaced it to ‘Hypersensitivity to ferric carboxymaltose or to any of the excipients of the study medication’. The authors have also made alterations to Fig. 1. Corrected Fig. 1 and Table 2 are given below:

The original article can be found online at <https://doi.org/10.1007/s13300-017-0330-z>.

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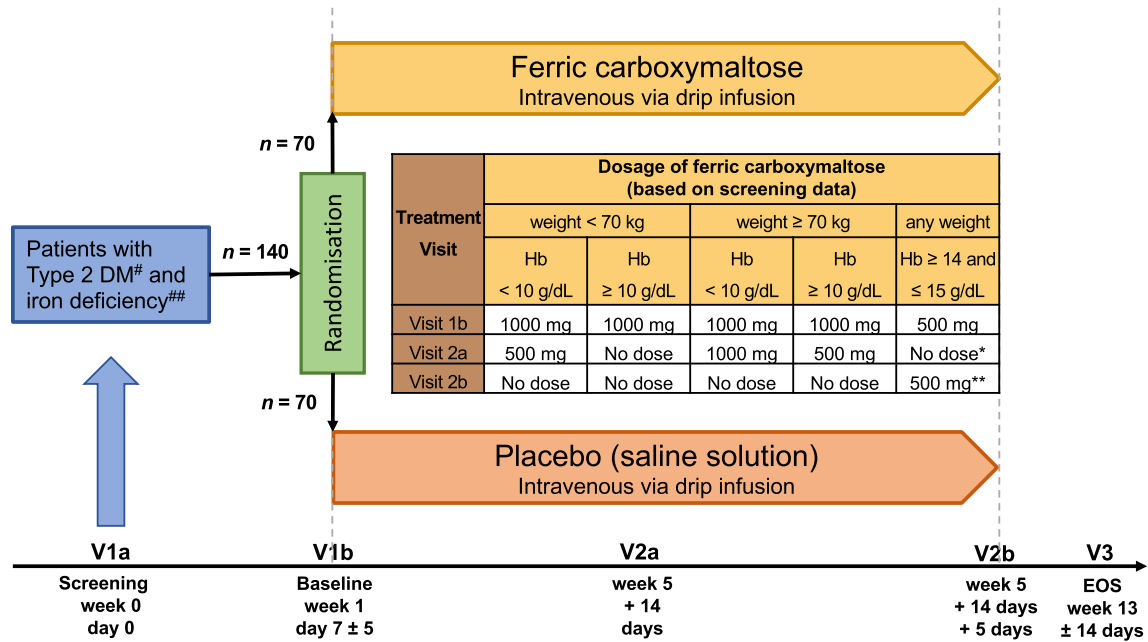


Fig. 1 CLEVER study design. [#]Defined as HbA1c ≥ 48 mmol/mol (6.5%) and < 69 mmol/mol (8.5%). ^{##}Defined as serum ferritin < 150 ng/mL or transferrin saturation < 25% if hemoglobin < 14 g/dL or serum ferritin < 100 ng/mL or transferrin saturation < 20% if hemoglobin ≥ 14 g/dL and ≤ 15 g/dL.

*Control parameter: ferritin and transferrin saturation.
 **If still iron deficient at V2a [serum ferritin < 150 ng/mL or transferrin saturation < 25%], an additional dose of 500 mg ferric carboxymaltose is given at V2b, otherwise it is not

Table 2 Key inclusion and exclusion criteria

Key inclusion criteria	Men and women older than 18 years
	Diagnosis of type 2 diabetes and iron deficiency defined as follows:
	HbA1c \geq 48 mmol/mol (6.5%) and $<$ 69 mmol/mol (8.5%)
	Serum ferritin $<$ 150 ng/mL or transferrin saturation $<$ 25% if hemoglobin $<$ 14 g/dL
	Serum ferritin $<$ 100 ng/mL or transferrin saturation $<$ 20% if hemoglobin \geq 14 g/dL and \leq 15 g/dL
Key exclusion criteria	Continuous subcutaneous insulin infusion
	Thalassemia
	Hemoglobin $>$ 15 g/dL (\geq 9.31 mmol/L)
	C-reactive protein $>$ 15 mg/L
	Change in HbA1c of more than \pm 0.3% within the last 3 months
	Hypersensitivity to ferric carboxymaltose or to any of the excipients of the study medication
	Known serious hypersensitivity to other parenteral iron products
	History of acquired iron overload
	History of erythropoietin-stimulating agent, IV or high-dose oral iron therapy or blood transfusion $<$ 12 weeks prior to randomization
	Body weight \leq 40 kg
	Chronic or active liver disease
	Vitamin B12 and/or serum folate deficiency
	Current malignancy under treatment
	Renal function GFR $<$ 30 mL/min/1.73 m ²
	Significant major cardiovascular disease ongoing or in the past 3 months
	Polyneuropathy without ischemia
Pregnant or nursing (lactating) women	
Any person not willing to use adequate contraceptive precautions during the study and for up to 5 days after the last scheduled dose of study medication	

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