CHRONIC KIDNEY DISEASE. ANAEMIA

IRON ISOMALTOSIDE 1000 (MONOFER®) COMPARED TO ORAL IRON SULPHATE IN EUROPEAN PATIENTS WITH NON-DIALYSIS DEPENDENT CHRONIC KIDNEY DISEASE (NDD-CKD)

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Introduction and Aims: Iron deficiency anaemia is common in patients with chronic kidney disease (CKD). As the rationale for prescribing iron to kidney patients may differ in different international regions, we analysed a subset of data from European patients who were part of a global trial comparing the efficacy and safety of intravenous (IV) iron isomaltoside 1000 and oral iron sulphate in patients with non-dialysis dependent (NDD)-CKD.

Methods: The trial was an open-label, comparative, multi-centre trial conducted in NDD-CKD patients randomized 2:1 to either IV iron isomaltoside 1000 (group A) or iron sulphate administered as 100 mg elemental oral iron b.i.d. (200 mg daily) for 8 weeks (group B). The patients in group A were equally divided into A1: IV infusion of max 1000 mg single doses once weekly and A2: IV bolus injections of 500 mg administered once weekly until full replacement dose was achieved. Calculation of iron need was according to a modified Ganzoni formula (target Hb 13 g/dL, iron stores 500 mg). The primary objective was to demonstrate non-inferiority and the primary endpoint was change in Hb concentrations from baseline to week 4.

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Results: In this European subgroup, iron isomaltoside 1000 showed non-inferiority at week 4 (p < 0.0001) compared to oral iron and superiority at the end of the study at week 8 (p = 0.009). The Hb response was more pronounced with IV replacement doses >1000 mg. 93 % of patients in A1 obtained full iron replacement in one visit. Adverse drug reactions (ADRs) were observed in 17 % in group A and 26 % in group B. 1 patient in each group experienced a serious ADR. The frequency of a phosphate < 2 mg/dL was 3 % versus 2 % in groups A and B, respectively. No event of hypophosphatemia was considered as an adverse event. 9 % of the patients treated with oral iron withdrew from the study due to adverse events, whereas none were withdrawn in group A due to an adverse event (p = 0.017).

Conclusions: In this sub-analysis iron isomaltoside 1000 was more efficacious after 8 weeks than oral iron in increasing haemoglobin. Iron isomaltoside 1000 was well-tolerated at the tested dose levels in European NDD-CKD patients. Significantly more patients treated with oral iron withdrew from the study due to adverse events as compared to patients treated with iron isomaltoside 1000.