**INTRODUCTION AND AIMS:** Iron deficiency anaemia (IDA) is a major health problem worldwide and it is common in patients with chronic kidney disease (CKD). Intravenous administration of high-dose iron is the most efficient approach to replenish iron stores. The present analysis evaluated safety and efficacy of high dose iron isomaltoside in CKD patients with IDA.

**METHODS:** This was a pooled analysis of 3 trials of iron isomaltoside performed in CKD patients (391 dialysis and 249 non-dialysis CKD patients) with IDA [1−3]. Outcome measures were frequency of adverse drug reactions (ADRs) and change in haemoglobin (Hb).

**RESULTS:** 640 patients (373 men, 267 women) were included in the analysis. Cumulative doses of either ≤1000 mg or >1000 mg iron isomaltoside were administered in 597 and 43 patients, respectively. Median baseline Hb was 10.8 and 9.0 g/dL, ferritin was 238 and 112 ng/mL, and TSAT was 19 and 14% in patients dosed with ≤1000 mg and >1000 mg iron isomaltoside, respectively. ADRs were observed in 7.5% (59 events in 45 patients) and 9.3% (5 events in 4 patients) of the patients dosed with ≤1000 mg and >1000 mg iron isomaltoside, respectively (p=0.6). In patients dosed with ≤1000 mg iron isomaltoside, Hb increased with a mean of 0.25 (95% confidence interval [CI]: 0.05) g/dL from baseline to week 3, 0.29 (0.04) g/dL to week 4, and 0.57 (0.04) g/dL to week 8. In patients dosed with >1000 mg iron isomaltoside, Hb increased with a mean of 0.35 (0.16) g/dL from baseline to week 3, 0.40 (0.14) g/dL to week 4, and 0.88 (0.14) g/dL to week 8. The observed increase in Hb was higher in patients dosed with >1000 mg iron isomaltoside from week 3, and was statistically significantly higher at week 8 (p=0.03) (Figure 1).

**CONCLUSIONS:** Across trials, no dose-response for ADRs was observed with administration of high cumulative doses of iron isomaltoside, moreover a greater Hb increase was observed after 3 weeks with doses >1000 mg. Thus, high doses (>1000 mg) of iron isomaltoside can be administered without additional safety concerns and with efficacious increases in Hb in CKD patients with IDA.

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**Figure 1:** Change in haemoglobin (g/dL) over time.