

**THE RELATIONSHIP BETWEEN HEMOGLOBIN LEVELS,  
ESA USE, AND ADVERSE EVENTS IN CKD PATIENTS  
TREATED WITH IV FERUMOXYTOL**

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Ferumoxytol is a carbohydrate-coated iron oxide with evidence for a lower free iron content than other IV irons. Registrational trials of ferumoxytol in CKD patients on and not on dialysis have demonstrated increases in hemoglobin (Hb) levels and a favorable safety profile vs. oral iron. Two Phase III trials in non-dialysis CKD patients compared ferumoxytol vs. oral iron in patients receiving and not receiving erythropoiesis-stimulating agents (ESAs). Given that adverse clinical outcomes have been observed in trials targeting higher vs. lower Hb levels with ESAs, we explored the association between changes in Hb, maximum achieved Hb, ESA use, and adverse events (AEs) in ferumoxytol vs. oral iron-treated patients. A total of 437 patients (170 receiving ESAs) were treated with two IV injections of 510 mg ferumoxytol given in under a minute within 5 days, and 149 patients (65 receiving ESAs) were treated with 200 mg/day of PO elemental iron for 21 days. Hb was measured at Day 35. Within the ferumoxytol group, there were no clear trends for subject incidences of AEs across Hb change quartiles (range: 41.2 to 48.1%), max. Hb quartiles (range: 43.0 to 47.2%), and ESA categories (44.2% on ESAs and 48.2% not on ESAs). In addition, AE rates were generally similar or lower in ferumoxytol- vs. oral iron-treated patients across Hb and ESA categories. These data support the tolerability of ferumoxytol vs. oral iron in non-dialysis CKD patients in the presence and absence of ESA use across a range of Hb levels.