A RANDOMIZED TRIAL INVESTIGATING THE EFFECTS OF ORAL LIPOSOMIAL IRON VERSUS INTRAVENOUS IRON GLUCONATE IN CKD HEMODIALYSIS PATIENTS

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**Background.** This study aimed to investigate the efficacy and tolerability of liposomal oral iron in comparison to intravenous iron gluconate in CKD patients undergoing chronic hemodialysis. Liposomal iron is a new iron formulation with high bioavailability and a low incidence of side effects and it is highly tolerated. The use of intravenous iron in hemodialysis patients treated in an out-hospital setting is still under debate.

**Methods.** Twelve chronic HD patients undergoing regular intravenous iron therapy and ESAs treatment were randomized 1:1 to receive iron liposomal iron (Sideral®, PharmaNutra) or to continue iron gluconate intravenous treatment for three months. Oral liposomal iron was administered in a comparable weekly dosage (from 30 to 180 mg/week) The primary end point was to evaluate the effects of the two different treatments on Hb levels; the iron status, compliance and adverse effects were also evaluated. All patients received alfa EPO and iron and ESAs dose were not changed during the study period.

**Results.** No significant variations were observed in the two groups at the follow-up time. Hemoglobin levels varied from 12.03±1.8 g/dL to 12.57±2.1 g/dL in the intravenous group and from 12.68±2.3 g/dL to 12.66 g/dL (p= n.s.) in the oral group. Iron saturation index varied from 27.6 to 30.8% in the iron group and from 24 to 21% in the oral group (p= n.s.). Oral iron was highly tolerated.

**Conclusions.** Oral liposomal iron is a safe and efficacious alternative to iron gluconate therapy in chronic hemodialysis patients. Further studies are needed to investigate iron liposomal effects in severely inflamed patients.