LIPOSOMIAL IRON FOR THE TREATMENT OF IRON DEFICIENCY ANEMIA IN NON-DIALYSIS CHRONIC KIDNEY DISEASE PATIENTS: A RANDOMIZED CONTROLLED TRIAL

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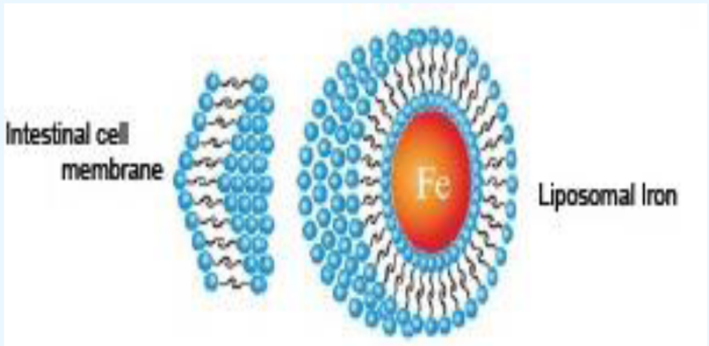
Objectives:

Iron deficiency frequently complicates anemia in patients with non dialysis-dependent chronic kidney disease (ND-CKD). The optimum route of administration of iron is controversial in ND-CKD patients: although oral iron is less expensive, easier to administer, and may be safer it can be compromised by gastrointestinal side effects that can result in poor patient compliance and suboptimal iron absorption.

The aim of this study is to determine if liposomial iron, a preparation of ferric pyrophosphate encapsulated in a phospholipid membrane is as effective as endovenous (ev) iron for the treatment of iron-deficiency anemia in ND-CKD patients.



When intestinal cell membrane comes into contact with liposome, it becomes more fluid and provides for maximum absorption of iron contained therein

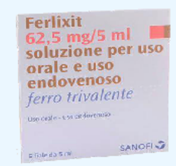
Methods:

This was an open label, phase IV, prospective randomized controlled trial. A total of 99 patients with CKD 3-5 stage not on dialysis (eGFR <60 ml/min/1.73 m2) and anemia secondary to absolute or functional iron deficiency (hemoglobin ≤ 12g/dL; ferritin ≤ 100ng/mL or ferritin between 100 and 300 ng / mL with TSAT ≤ 25%) were enrolled and randomized in a 1:2 ratio

ORAL IRON GROUP 66 pz

Pyrophosphate liposomal iron 30mg/die plus ascorbic acid 70mg/die for three months

E.V. IRON GROUP 33 pz



A total dose of 1000 mg of iron gluconate divided into weekly administrations of 125mg diluted in 250 mL normal saline

Primary outcome:The primary outcome variable was change from baseline (CFB) in haemoglobin (Hb) values at any time point of the study in the two groups. We determined the full panel of hematologic and iron indices at enrollment (T0) and months 1 (T1), 2 (T2), 3 (T3) and 4 (T4)

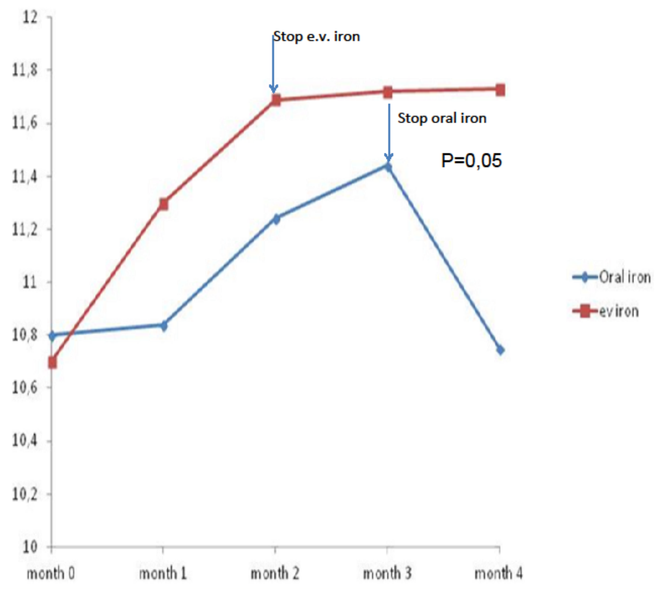
Results:

Both groups had similar baseline characteristics. 3 patients in oral group and only one in ev group recieved ESA therapy. Hb concentrations increased from baseline in both groups at T1, T2, T3 but were higher at every study time point during ev treatment (Figure 1); Hb decreased when oral iron was stopped, remained stable after the suspension of ev iron. In oral group only at T3 the CFB in Hb was significant (0.6±0.67 gr/dL, p=0.05), in ev group the CFB was significantly (p <0.05) at T1 (0.6 ±0.91 gr/dL), T2 (0.89 ± 1.09 gr/dL), T3 (0.92 ±1.0 gr/dL) and T4 (0.93 ±0.94 gr/dL). CFB in Hb values were different at T1 (P<0.003) e T2 (P<0.027) in the two groups, they became similar at T3 (p =ns) and different again at T4 (P<0.0001). In comparison to oral iron , ev iron achieved greater and significant improvements in ferritin and TSAT. No side effects were reported in oral group; the most common side effect reported with ev iron was hypotension

Basal variables	Oral iron group (N=66)	E.v. iron group (N=33)	P value *
Sex (F)	50	20	0.77
Age (mean ± SD)	53.5 ±15	47.6 ± 16	0.12
ESA (YES)	3 (5%)	1 (4%)	0.84
BMI (kg/m2)	26.7 ± 4.4	25.6 ±4.9	0.34
Vitamin B12	522.7 ± 239	443 ± 152	0.10
Folate	6.36 ± 3.12	6.34 ± 2.3	0.98
GFR (ml/min)	25.9 ±11.4	31.8 ± 12.9	0.07
PCR	0.60 ±0.76	0.47 ±0.33	0.29
PTH (pg/ml)	140 ± 113	111 ±63	0.26
Serum iron (mcg/dl)	61.3 ±2.7	58.5 ± 23.4	0.6
Ferritin	73.8 ± 70.8	117.5 ±140	0.19
TIBC	313.4 ±7.7	324 ±10	0.43
TSAT	0.20 ±0.06	0.18 ±0.08	0.25
Hemoglobin (gr/dl)	10.8 ±0.57	10.7 ± 0.77	0.82

Graphs and tables

Figure 1: Mean haemoglobin values by treatment group overtime



Conclusions:

Oral liposomial iron increases significantly Hb values in anemic ND-CKD patients after three months of therapy; these increments were similar to the ones obtained after the administration of 1000 mg of ev gluconate iron. Liposomial iron is well tolerated and this regime can offer an alternative to ev iron supplementation for the treatment of iron-deficiency anemia in ND-CKD patients

References:

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H) Clinical Nephrology, CKD. H3) Anaemia in CKD 1-5.
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