Abstracts Isofer

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Ferrous bisglycinate 25 mg iron is as effective as ferrous sulfate 50 mg iron in the prophylaxis of iron deficiency and anemia during pregnancy in a randomized trial.

Milman N, Jønsson L, Dyre P, Pedersen PL, Larsen LG.

OBJECTIVE:

To compare the effects of oral ferrous bisglycinate 25 mg iron/day vs. ferrous sulfate 50 mg iron/day in the prevention of iron deficiency (ID) and iron deficiency anemia (IDA) in pregnant women.

DESIGN:

Randomized, double-blind, intention-to-treat study.

SETTING:

Antenatal care clinic.

SAMPLE:

80 healthy ethnic Danish pregnant women.

METHODS:

Women were allocated to ferrous bisglycinate 25 mg elemental iron (Aminojern®) (n=40) or ferrous sulfate 50 mg elemental iron (n=40) from 15 to 19 weeks of gestation to delivery. Hematological status (hemoglobin, red blood cell indices) and iron status (plasma iron, plasma transferrin, plasma transferrin saturation, plasma ferritin) were measured at 15-19 weeks (baseline), 27-28 weeks and 36-37 weeks of gestation.

MAIN OUTCOME MEASURES:

Occurrence of ID (ferritin <15 μg/L) and IDA (ferritin <12 μg/L and hemoglobin <110 g/L).

RESULTS:

At inclusion, there were no significant differences between the bisglycinate and sulfate group concerning hematological status and iron status. The frequencies of ID and IDA were low and not significantly different in the two iron groups. The frequency of gastrointestinal complaints was lower in the bisglycinate than in the sulfate group (P=0.001). Newborns weight was slightly higher in the bisglycinate vs. the sulfate group (3601±517 g vs. 3395±426 g, P=0.09).

CONCLUSIONS:

In the prevention of ID and IDA, ferrous bisglycinate was not inferior to ferrous sulfate. Ferrous bisglycinate in a low dose of 25 mg iron/day appears to be adequate to prevent IDA in more than 95% of Danish women during pregnancy and postpartum.

Arch Latinoam Nutr. 2001 Mar;51(1 Suppl 1):7-12.

The chemistry of ferrous bis-glycinate chelate.

Ashmead SD[1].

In order to produce a ferrous chelate four criteria must be met: 1) the ligand must contain two functional groups which are capable of entering into covalent and coordinate covalent bonds; 2) a ring structure with the ferrous ion being the closing member of the ring must be created; 3) the chelate must be sterically possible; and 4) the chelation reaction must be energetically possible. In addition to the above, a totally nutritionally functional ferrous chelate must meet three further criteria: 1) it must have low molecular weight; 2) its stability constant must be nutritionally functional; and 3) the ligand must be metabolizable by the body. When ferrous iron is reacted with glycine and forms a bis-glycinate chelate, it meets all of the requirements of being both a chelate and being a totally nutritionally functional chelate.

Minerva Pediatr. 2016 Nov 10. [Epub ahead of print]

Oral iron absorption test with ferrous bisglycinate chelate in children with celiac disease: preliminary results.

Mazza GA[1], Pedrelli L, Battaglia E, Giancotti L, Miniero R.

BACKGROUND:

Celiac disease (CD) is an immunologically-mediated enteropathy resulting in small-bowel mucosal villous atrophy with crypt hyperplasia. Iron malabsorption is usually observed in CD. Only few studies investigated oral iron absorption in subjects with gastrointestinal diseases and Iron Deficiency Anemia (IDA), using the oral iron absorption test (OIAT). We considered useful to investigate the OIAT, using Ferrous Bisglycinate Chelate (FBC), in patients with CD at diagnosis or on Gluten Free Diet (GFD) from at least 1 year.

METHODS:

A total of 25 patients with CD (3-18 years old) and iron depletion, at diagnosis of CD (n=12) or on GFD from at least 12 months (n=13), were considered. Serum iron was evaluated at baseline (T0) and after 3 hours (T1) from the oral iron ingestion. Statistical analyses were conducted using SPSS 21.0 software for Mac.

RESULTS:

OIAT was well tolerated by all patients. An important increase of the serum iron at T1, of at least twice the baseline values, occurred in all patients except in one (p-value <0.0005).

CONCLUSIONS:

These results demonstrated good efficacy of the FBC, not only in patients with CD on GFD but also in children with newly diagnosed CD with the characteristic intestinal lesions.

Biomed Pharmacother. 2012 Sep;66(6):414-8. doi: 10.1016/j.biopha.2012.06.003. Epub 2012 Jun 29.

Treatment of mild non-chemotherapy-induced iron deficiency anemia in cancer patients: comparison between oral ferrous bisglycinate chelate and ferrous sulfate.

Ferrari P[1], Nicolini A, Manca ML, Rossi G, Anselmi L, Conte M, Carpi A, Bonino F.

In cancer patients mild-moderate non-chemotherapy-induced iron deficiency anemia (IDA) is usually treated with oral iron salts, mostly ferrous sulfate. In this study, we compare efficacy and toxicity of oral ferrous bisglycinate chelate and ferrous sulfate in cancer patients with mild IDA. Twenty-four patients operated on for solid tumors (10 breast, 12 colorectal, 2 gastric), aged 61±10 years (range 45-75), with non-chemotherapy-induced hemoglobin (Hb) values between 10 and 12 g/dL and ferritin lower than 30 ng/mL were randomized to receive oral ferrous bisglycinate chelate, 28 mg per day for 20 days, and then 14 mg per day for 40 days (12 patients) (A group) or oral ferrous sulphate, 105 mg per day for 60 days (12 patients) (B group). Values of hemoglobin and ferritin obtained at diagnosis, 1 and 2 months from the beginning of treatment were compared. Adverse events (AEs) related to the two treatments were recorded. In the 12 patients treated with ferrous bisglycinate chelate, basal hemoglobin and ferritin values (mean±SD) were 11.6±0.8 g/dL and 16.1±8.0 ng/mL. After 2 months of treatment, they were 13.0±1.4 g/dL and 33.8±22.0 ng/mL, respectively (P=0.0003 and P=0.020). In the group treated with ferrous sulphate, hemoglobin and ferritin mean values were 11.3±0.6 g/dL and 19.0±6.4 ng/mL basally, and 12.7±0.70 g/dL and 40.8±28.1 ng/mL (P<0.0001 and P=0.017) after 2 months of treatment. AEs occurred in six cases. In all these six cases, two (17%) treated with ferrous bisglycinatechelate and four (33%) with ferrous sulphate, toxicity was grade 1. In conclusion, these data suggest that ferrous bisglycinate chelate has similar efficacy and likely lower GI toxicity than ferrous sulphate given at the conventional dose of 105 mg per day for the same time.

Br J Nutr. 2006 Mar;95(3):532-8.

The efficacy of ferrous bisglycinate and electrolytic iron as fortificants in bread in iron-deficient school children.

van Stuijvenberg ME[1], Smuts CM, Wolmarans P, Lombard CJ, Dhansay MA.

Food fortification is an important long-term strategy for addressing micronutrient deficiencies. Finding the ideal Fe fortification compound, however, remains a challenge. In the present study the effect of ferrous bisglycinate as fortificant in brown bread was compared with that of electrolytic Fe among Fe-deficient school children in a randomised controlled trial. Children (n 160), aged 6-11 years, with serum ferritin <20 microg/l, were randomly assigned to one of three treatment categories: (i) standard unfortified bread; (ii) bread with electrolytic Fe as fortificant; and (iii) bread with ferrous bisglycinate as fortificant. Each child received four slices of bread (120 g) on school days, which supplied an average of 3.66 mg elemental Fe per intervention day for 137 d (2.52 mg/d for 75 d and 5.04 mg/d for 62 d) over a period of 7.5 months. Hb, serum ferritin, serum Fe and transferrin saturation were measured at baseline and at the end of the intervention. Significant treatment effects were observed for Hb (P = 0.013), serum Fe (P = 0.041) and transferrin saturation (P = 0.042) in the ferrous bisglycinategroup, but not in the electrolytic Fe group. There were no significant intervention effects for serum ferritin in either treatment group. Overall, ferrous bisglycinate as Fe fortificant in brown bread performed better than electrolytic Fe in a group of Fe-deficient school children over a period of 7.5 months.

Food Chem Toxicol. 1999 Jul;37(7):723-31.

Safety evaluation of ferrous bisglycinate chelate.

Jeppsen RB[1], Borzelleca JF.

Ferrous bisglycinate chelate (Ferrochel) is a highly stable chelate that can be added to most foods. Data from human and animal studies indicate that the ferrous iron is readily bioavailable with fewer side-effects than the more commonly used iron salts. The acute oral LD50 for male and female Sprague-Dawley (S-D) rats is 2800 mg/kg body weight (560 mg/kg body weight iron [confidence limit (CL) 399-786] as the active ingredient). Male and female CD (Sprague Dawley-derived) rats were fed ferrous bisglycinate as a dietary admixture at doses of 0, 100, 250 and 500 mg/kg body weight/day. There were no biologically or statistically significant dose-related differences between the control and treated animals with respect to body weight gain, food consumption, food efficiency, behavioural effects, clinical chemistries, haematology, absolute and relative organ weights, or gross and microscopic findings. Hepatic non-heme iron concentrations were elevated, indicating that the ferrous iron had been absorbed. The no-observed-adverse-effect level (NOAEL) was 500 mg/kg body weight/day, the highest dose tested.

Arch Latinoam Nutr. 2001 Mar;51(1 Suppl 1):42-7.

Relative effectiveness of iron bis-glycinate chelate (Ferrochel) and ferrous sulfate in the control of iron deficiency in pregnant women.

Szarfarc SC[1], de Cassana LM, Fujimori E, Guerra-Shinohara EM, de Oliveira IM.

The relative effectiveness of daily supplementation of iron deficiency during pregnancy using 15 mg/day of iron from iron-bis-glycinate chelate (71 pregnant women), or 40 mg iron from ferrous sulfate (74 pregnant women) was evaluated by measuring hemoglobin, transferrin saturation and serum ferritin, at the beginning of the study (< 20 weeks of pregnancy) and at 20-30 weeks and 30-40 weeks thereafter. Ingestion for 13 weeks or more was considered adequate. Seventy three percent of the Ferrochel consuming group and 35% of the ferroussulfate consuming group were considered to have taken the treatment adequately. The decrease in levels of all the measured parameters was significantly less pronounced in the group that consumed Ferrochel in spite of the lower treatment dose. Iron depletion was found in 30.8% of the women treated with Ferrochel and in 54.5% of the women than consumed ferrous sulfate. Of the factors responsible for non compliance taste was reported in 29.8% of the ferrous sulfate consumers and none in the groups that consumed Ferrochel. It is concluded that daily supplementation with Ferrochel was significantly more effective, in spite of the lower dose, than supplementation with ferroussulfate.

Arch Latinoam Nutr. 2001 Mar;51(1 Suppl 1):22-5.

Bioavailability of iron bis-glycinate chelate in water.

Olivares M[1], Pizarro F.

Iron amino acid chelate is being increasingly considered in programs for iron fortification of foods. The bioavailability of iron bis-glycinatechelate given in water was studied using a double-isotopic method in a group of 14 women. Iron absorption from aqueous solutions of 15 mg/L of elemental iron as either iron bis-glycine chelate or ferrous ascorbate was not significantly different (34.6% and 29.9% respectively). Standardized iron absorption of the iron bis-glycinate was 46.3% (standardized to 40% absorption of the reference dose). There was a significant correlations between (ln) iron absorption of iron bis-glycinate chelate with (ln) serum ferritin ($r = -0.60$, $p < 0.03$) and with (ln) iron absorption from ferrous ascorbate ($r = 0.71$, $p < 0.006$), suggesting that iron bis-glycinate chelate absorption is indeed regulated by the iron stores of the body.

Nutrition. 2001 May;17(5):381-4.

Effectiveness of treatment of iron-deficiency anemia in infants and young children with ferrousbis-glycinate chelate.

Pineda O[1], Ashmead HD.

Forty infants, 6 to 36 mo old, with iron-deficiency anemia (hemoglobin < 11 g/dL) were matched and assigned to two groups. One group received FeS0(4) and the other received ferrous bis-glycinate chelate at a dose of 5 mg of Fe daily per kilogram of body weight for 28 d. Both groups had significant hemoglobin increases (P < 0.001), but only the group treated with ferrous bis-glycinate chelate had significant increases (P < 0.005) in plasma ferritin. Apparent iron bioavailabilities were calculated at 26.7% for FeS0(4) and 90.9% for ferrous bis-glycinate chelate. Regression analysis indicated that absorption of both sources of iron were similarly regulated by the body according to changes in hemoglobin. We concluded that ferrous bis-glycinate chelate is the iron of choice for the treatment of infants with iron-deficiency anemia because of its high bioavailability and good regulation.

Int J Vitam Nutr Res. 2004 Nov;74(6):435-43.

Iron amino acid chelates.

Hertrampf E[1], Olivares M.

Iron amino acid chelates, such as iron glycinate chelates, have been developed to be used as food fortificants and therapeutic agents in the prevention and treatment of iron deficiency anemia. Ferrous bis-glycine chelate (FeBC), ferric tris-glycine chelate, ferric glycinate, and ferrousbis-glycinate hydrochloride are available commercially. FeBC is the most studied and used form. Iron absorption from FeBC is affected by enhancers and inhibitors of iron absorption, but to a lesser extent than ferrous sulfate. Its absorption is regulated by iron stores. FeBC is better absorbed from milk, wheat, whole maize flour, and precooked corn flour than is ferrous sulfate. Supplementation trials have demonstrated that FeBC is efficacious in treating iron deficiency anemia. Consumption of FeBC-fortified liquid milk, dairy products, wheat rolls, and multi-nutrient beverages is associated with an improvement of iron status. The main limitations to the widespread use of FeBC in national fortification programs are the cost and the potential for promoting organoleptic changes in some food matrices. Additional research is required to establish the bioavailability of FeBC in different food matrices. Other amino acid chelates should also be evaluated. Finally there is an urgent need for more rigorous efficacy trials designed to define the relative merits of amino acid chelates when compared with bioavailable iron salts such as ferrous sulfate and ferrous fumarate and to determine appropriate fortification levels.