

Effects of Micronised Dispersible Ferric Pyrophosphate combined with Alpha-Lactalbumin in pregnant women affected by Iron Deficiency Anemia: preliminary results from a prospective, double-blind, randomized controlled trial

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Context: Treatment of Iron-Deficiency Anemia (IDA) during pregnancy represent high priority targets in order to prevent adverse maternal-fetal outcomes.

Objective: This study aimed at evaluating the effects obtained by administering 30 mg of Micronised Dispersible Ferric Pyrophosphate (MDFP) plus 300 mg of Alpha-Lactalbumin (MDFP-AL) compared to 80 mg of Ferrous Gluconate (FG) in pregnant women affected by IDA.

Methods: Prospective, double-blind, randomized controlled trial.

Patients: We considered eligible all second-trimester singleton pregnancies in women affected by IDA. We excluded any other disease, twin pregnancies, any other pharmacologic/nutraceutical treatment (besides folic acid) before/during pregnancy.

Interventions: We randomized patients in two groups: one underwent treatment with 1 tablet of MDFP-AL/day, the other one with 1 tablet of FG/day, for 30 days.

Main Outcome Measures: We evaluated hemoglobin (Hb), ferritin, red blood cells (RBCs), serum iron, hematocrit (Hct), and side effects at baseline (T0), after 15 days (T1) and 30 days (T2).

Results: 50 women met the inclusion/exclusion criteria. We did not observe significant differences between the two groups for mean age, gestational age at the enrollment and parity. In MDFP-AL group, after 15 days (T1) Hb, ferritin, serum iron and Hct and were significantly improved respect to baseline (T0); after 30 days (T2), all the parameters, including RBCs, were significantly improved respect to baseline (T0). Similarly, in FG group the investigated parameters were improved both after 15 (T1) and 30 days (T2) respect to baseline (T0), although less in percentage terms respect to MDFP-AL group. The side effects rate was 24% in FG group, whereas MDFP-AL group did not show any significant side effect.

Conclusion: Overall, MDFP-AL is more effective and safe than FG for the treatment of IDA in pregnant women.

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