2023. POPEYE

RCT/Iron/pediatric IBD/

Ferric Carboxymaltose Versus Ferrous Fumarate in Anemic Children with Inflammatory Bowel Disease: The POPEYE Randomized Controlled Clinical Trial

Multicenter, randomized trial.
Pediatric IBD patients (age 8-18) with anemia were randomized to IV dose of ferric carboxymaltose or 12 weeks of oral ferrous fumarate.

Primary endpoints: Change in the 6-minute walking distance (6MWD) from baseline, expressed as Z-score.

Results: N=64

- At week 4 the 6MWD z-score decreased 0.71 in IVferric vs 0.11 oralferrous.
- At 3 and 6 month follow-up, no significant differences in 6MWD were observed.
- Haemoglobin gradually increased in both groups with no differences of the rate of increase at 1,3 and 6 months.
- Adverse events ocurred in 16% on IVferric vs 21%oralFerrous.
- Hypophosphatemia was not detected.

Conclusion:
A single dose of IV ferric carboxymaltose was superior to oral ferrous fumarate with respect to quick improvement of physical fitness. At 3 and 6 months after initiation of therapy, no differences between oral and IV therapies. The increase of Hb over time was comparable in both treatment groups.

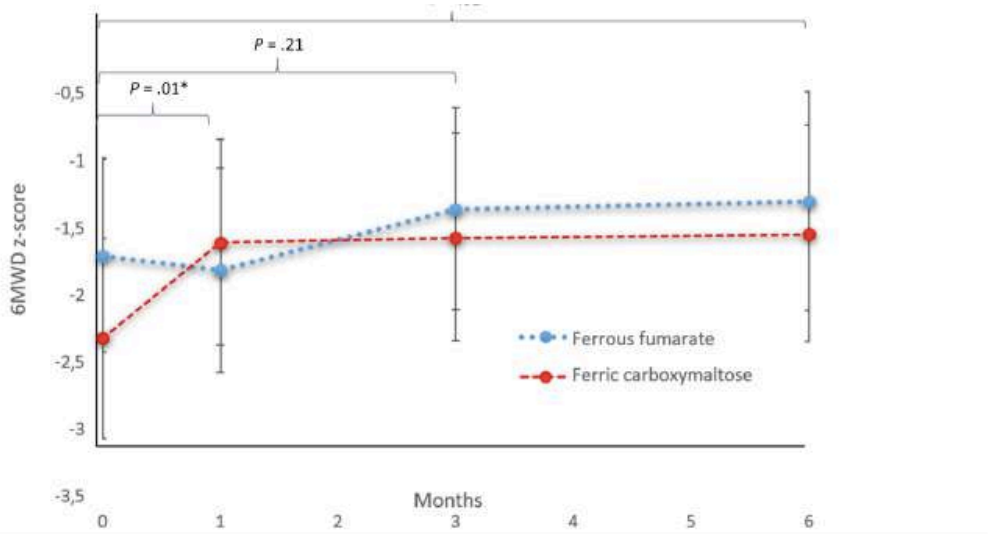

Figure 3. Increase in mean 6-minute walking distance z-score and 95% CIs over time in participants assigned to ferric carboxymaltose (*red line*) and ferrous fumarate (*blue line*). * significant.

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