

Title: Effectiveness and safety of ferric carboxymaltose in Indian rural and tribal women with iron deficiency anemia



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Introduction: Iron deficiency anemia (IDA) is recognized by the World Health Organization as the most prevalent nutritional deficiency worldwide¹. More than half of Indian rural women (pregnant and non-pregnant) are anemic.² However, data on the effectiveness and tolerability of Ferric carboxymaltose (FCM) in women in rural and tribal India is limited.

Objectives: Primary objective of the present study was to assess the effectiveness of Intravenous (IV) infusion FCM in IDA in rural & tribal women. Secondary objectives were to assess change in hematological parameters from baseline, to assess Patients global impression of change (PGIC) score, safety and tolerability.

Materials and Methods: Prospective, open-label, observational, real world, single-center study was conducted in which female patients visiting to the Getwell Multispecialty hospital, Manchar, Pune with IDA (Pregnant: Hb 6 to <11 g/dL, non-pregnant: Hb: 6 to <12 g/dl) were recruited.

FCM was administered (cumulative mean dose:1000 mg) as an IV infusion & patients were followed-up at 6 weeks. Change in the hemoglobin (Hb) & other hematological parameters from baseline, PGIC score, were assessed. Adverse effects related to FCM were monitored.

Results:

- 55 patients completed the study. 7.27% & 92.73% of the patients were pregnant & non-pregnant respectively. Significant increase in Hb of 3.64 g/dL ($p < 0.001$) was recorded at 6 weeks.
- All pregnant women achieved the target Hb of 11 g/dL, while 58.82% of non-pregnant women reached 12 g/dL. The mean PGIC score was 6.49 ± 0.64 at end of 6 weeks, reflecting a strong overall satisfaction from the treatment.
- There was significant increase in Hct, MCV, MCH, MCHC ($P < 0.05$ for all) as compared to baseline. FCM infusion was well tolerated.

Conclusion: FCM IV infusion significantly increased Hb levels & also significantly improved other haematological parameters at 6 weeks. FCM appears to be effective & well-tolerated in treatment for IDA in pregnant & non-pregnant women in rural and tribal area.

Conflict of interest: Dr. Ketan Kulkarni, Dr. Shridevi Gundu, Dr. Sachin Suryawanshi and Dr. Prashant Katke are full time employees of Emcure Pharmaceuticals Ltd which actively markets FCM

References: 1. Kumar A, Sharma E, Marley A, Samaan MA, Brookes MJ. Iron deficiency anaemia: pathophysiology, assessment, practical management. BMJ Open Gastroenterology 2022;9:e000759, . 2. NFHS-5, 2019-21

Change in Hb levels from Baseline to Week 6 with FCM infusion

