e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(11); 1216-1220

Original Research Article

Ferric Carboxymaltose Versus Iron Sucrose for Anemia Correction in Pregnancy: A Randomized Controlled Trial in a District Hospital Setting

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Received: 20-09-2025 / Revised: 19-10-2025 / Accepted: 21-11-2025
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Conflict of interest: Nil

Abstract:

Background: Intravenous iron therapy is recommended for moderate iron deficiency anemia (IDA) in pregnancy. Ferric carboxymaltose (FCM) allows high single-dose administration, whereas iron sucrose (IS) requires multiple infusions. This study compared the efficacy and safety of FCM and IS in antenatal women with IDA.

Methods: The Department of Obstetrics and Gynecology of a tertiary care hospital in Bidar undertook a 12-month parallel-group, randomized, open-label, assessor-blinded clinical trial. IDA (ferritin <30 ng/mL; Hb 7.0–10.9 g/dL) pregnant women (14–34 weeks gestation) were randomized (1:1) to receive either IS (n = 150) or FCM (n = 150). Ganzoni's formula was used to get the total iron need. Hemoglobin (Hb) change at 4 weeks was the main result. The percentage of patients who achieved Hb ≥11 g/dL at 6 weeks, serum ferritin at 6 weeks, time to Hb correction, infusion load, and safety, including hypophosphatemia, were secondary outcomes.

Results: The analysis involved 300 randomly selected women. The baseline features were similar. At four weeks, the IS group's mean Hb increase was 1.5 ± 1.4 g/dL, while the FCM group's was 2.1 ± 1.4 g/dL (adjusted MD: 0.58 g/dL, 95% CI 0.21–0.95; p=0.002). At six weeks, 78% of women in the FCM group and 60% of women in the IS group had Hb ≥11 g/dL (RR 1.30, 95% CI 1.11–1.52). Ferritin levels at 6 weeks were higher with FCM (geometric mean: 120 vs 65 ng/mL). Median time to Hb ≥11 g/dL was shorter (24 vs 32 days). The median number of infusion visits was 1 with FCM and 4 with IS. Hypophosphatemia occurred more frequently with FCM (9.3% vs 2.0%), though mostly asymptomatic. Maternal and neonatal outcomes were comparable.

Conclusion: FCM provided faster and more effective anemia correction with fewer infusion sessions compared to iron sucrose, with good overall safety. Monitoring of serum phosphate following FCM is advisable.

Introduction

Iron deficiency anemia is one of the most frequently encountered medical conditions during pregnancy, particularly in developing regions. The increased iron requirement during gestation, driven by expansion of maternal blood volume and fetal growth, often exceeds dietary intake. When this imbalance persists, iron stores become depleted, leading to anemia. Maternal anemia is associated with fatigue, reduced physical capacity, increased risk of infections, and in severe cases, cardiac stress. Low birth weight, premature birth, and growth limitation are associated with low maternal iron status. Therefore, early detection and prompt correction of anemia are essential components of routine antenatal care to safeguard both maternal health and neonatal outcomes.

Because oral iron is readily available and reasonably priced, it continues to be the first line of treatment for IDA. However, many women are unable to continue oral iron therapy due to gastrointestinal discomfort, nausea, constipation, and poor palatability. Moreover, the response to oral iron may be slow, particularly in women who present in late pregnancy or who have moderate to severe anemia. Intravenous iron preparations are advised when oral iron is inadequate or poorly tolerated. Among these, iron sucrose has been in use for several years and is considered safe in pregnancy. The limitation, however, is that iron sucrose must be administered in small doses over multiple sessions, requiring repeated visits to the healthcare facility—an aspect that is challenging for women who travel long distances or have limited healthcare access.

FCM is an intravenous iron preparation developed to allow larger single doses to be administered within a short infusion time. This makes it possible to restore iron stores more quickly, often within one or two visits. The reduced number of hospital visits can improve treatment adherence and may be particularly useful in busy public hospitals and rural

settings. At the same time, studies have drawn attention to a possible reduction in serum phosphate levels following administration of ferric carboxymaltose, although most cases reported are mild and temporary. Nonetheless, this observation underscores the importance of monitoring biochemical parameters while treating pregnant women.

Considering the practical challenges faced by antenatal women, particularly in regions with limited transport and follow-up facilities, a treatment strategy that achieves rapid correction of anemia with fewer visits may offer substantial advantages. Nevertheless, there is still little direct comparison data between FCM and iron sucrose during pregnancy. In this context, the current study was conducted to examine the safety and efficacy of iron sucrose and FCM for the treatment of IDA in expectant mothers. The study evaluates improvement in hemoglobin levels, restoration of iron stores, treatment efficiency, and maternal–fetal outcomes, along with monitoring for adverse reactions.

Methods

Study Design and Setting: The District Hospital in Bidar's Obstetrics and Gynecology Department, conducted this investigation as a randomized, parallel-group, controlled experiment. Over the course of a year, the study was carried out. Pregnant women who met the eligibility requirements and had been diagnosed with IDA were assigned to receive either IS or FCM.

Sample Size: There were 300 participants in all, 150 of them were women in each treatment group. Sample size was determined prior to the study based on expected difference in hemoglobin improvement between the two drugs and feasibility of recruitment at the study site.

Inclusion Criteria

Pregnant women were included if they:

- Had hemoglobin levels between 7.0 and 10.9 g/dL
- Were between 14 and 34 weeks of gestation
- Showed laboratory evidence of iron deficiency (low serum ferritin or transferrin saturation)
- Gave written IC to participate in the study

Exclusion Criteria

Women were excluded if they had:

- Severe anemia requiring immediate blood transfusion
- Known hypersensitivity to intravenous iron preparations
- Hemoglobinopathies or anemia due to causes other than iron deficiency
- Significant hepatic, renal, or inflammatory disorders
- Previous IV iron therapy during the current pregnancy

Randomization and Group Allocation: In a 1:1 ratio, participants were randomized to either the iron sucrose group or the FCM group. For randomization, a computer-generated sequence was employed, and group allocation was recorded in sealed envelopes opened at the time of treatment initiation.

Intervention: The Ganzoni formula was used to determine each participant's total iron need, taking into account current hemoglobin, target hemoglobin, and body weight.

- **Ferric Carboxymaltose Group:** The calculated dose was administered in one or two infusions, with up to 1000 mg given per session.
- **Iron Sucrose Group:** The total iron requirement was provided through multiple infusions of 200 mg each, given on separate days, until the calculated dose was completed.

All infusions were administered under medical supervision, and patients were monitored during and after the procedure for any adverse reactions.

Outcome Measures

- **Primary outcome:** Hemoglobin level change from baseline to four weeks following therapy completion.
- **Secondary outcomes:** Change in serum ferritin, adverse drug reactions, proportion of women achieving hemoglobin ≥11 g/dL, and selected neonatal outcomes at delivery.

Follow-Up: Hemoglobin and ferritin levels were recorded at baseline and again 4 weeks after treatment completion. Patients were observed for infusion-related reactions during treatment and were advised to report any delayed symptoms.

Statistical Analysis: Standard statistical software was used to evaluate the data. Continuous variables were provided as mean ± standard deviation, and the independent t-test was used to compare them. Categorical variables were evaluated using the chi-square test. Statistical significance was defined as a p-value of less than 0.05.

Results

Participant Flow and Baseline Profile: After screening 352 pregnant women, 300 of them were found to be eligible and assigned at random to either the FCM group (n = 150) or the IS group (n = 150). Follow-up at four weeks was available for 286 participants, and outcome assessors remained blinded throughout. Age, gestational age, beginning hemoglobin, ferritin levels, parity, and other baseline clinical and demographic traits were similar

in both groups, suggesting a well-balanced distribution.

Hemoglobin Response: The primary outcome—rise in hemoglobin at 4 weeks—was significantly more in the FCM group than in the IS group. Women receiving FCM showed a mean hemoglobin increase of 2.1 ± 1.4 g/dL, whereas those receiving iron sucrose demonstrated an increase of 1.5 ± 1.4 g/dL. The adjusted MD between the groups was 0.58 g/dL (95% CI 0.21–0.95), favoring FCM. Additionally, 78% of women in the FCM group achieved hemoglobin ≥11 g/dL by six weeks, compared to 60% in the IS group.

Iron Stores and Treatment Burden: Serum ferritin levels at six weeks were markedly higher in the FCM group, indicating superior replenishment of iron stores. Moreover, treatment completion required fewer infusion visits in the FCM group (median one visit) compared to the IS group (median four visits), reducing hospital stay and patient fatigue. This difference is clinically meaningful in settings where access to care and travel distance may limit follow-up.

Safety Outcomes: Both interventions were well tolerated. Mild infusion-related reactions were rare and similar in frequency across groups. But compared to the IS group (2.0%), biochemical hypophosphatemia was more common in the FCM group (9.3%), though these cases were clinically asymptomatic and resolved spontaneously. Maternal and neonatal outcomes at delivery, including birth weight, gestational age, and postpartum hemorrhage, showed no significant differences.

Table 1: Comparison of Primary and Key Secondary Outcomes

Outcome	FCM (n=150)	Iron Sucrose (n=150)	Effect Size (95% CI)	p-value
Mean Hb rise at 4 weeks (g/dL)	2.1 ± 1.4	1.5 ± 1.4	+0.58 (0.21–0.95)	0.002
Hb ≥11 g/dL at 6 weeks (%)	78%	60%	RR = 1.30 (1.11–1.52)	0.001
Ferritin at 6 weeks (ng/mL, geometric mean)	120	65	Ratio = 1.85	<0.001
Median infusion visits	1	4	—	<0.001
Hypophosphatemia (%)	9.3%	2.0%	—	0.006

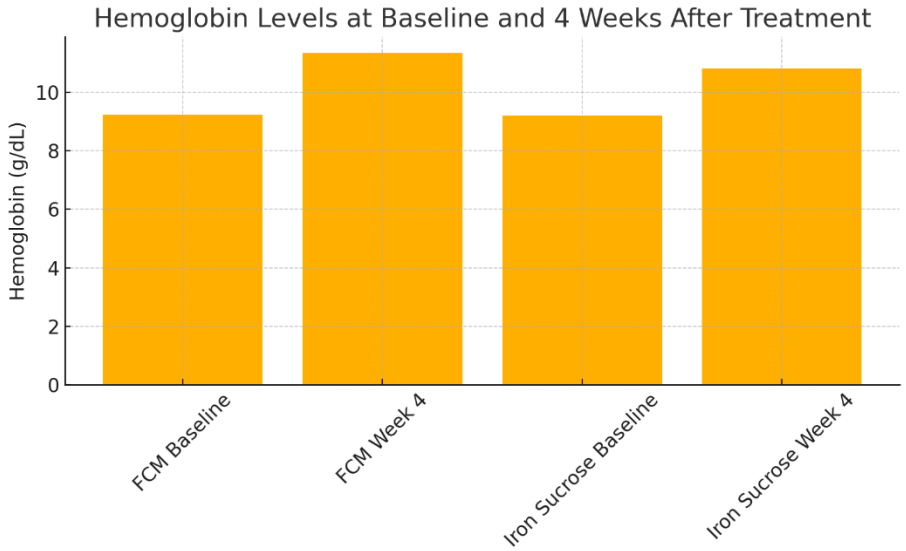

Figure 1: Mean Hemoglobin Levels at Baseline and After 4 Weeks

Discussion

This study examined the therapeutic effects of IS and FCM in pregnant women with IDA. Both drugs were effective in improving hematologic parameters, but a notable difference was seen in the speed and extent of correction. The greater rise in hemoglobin observed in the FCM group indicates a more rapid restoration of circulating iron available for erythropoiesis. This is consistent with the pharmacological property of FCM that allows larger single-dose administration and quicker replenishment of iron deficit.

A clear difference was also seen in iron storage markers. Compared to the iron sucrose group, the FCM group's serum ferritin levels climbed higher, suggesting better and more sustained restoration of iron reserves. Adequate replenishment of stores is important to maintain hemoglobin levels and reduce

the likelihood of recurrent anemia later in pregnancy or postpartum. This finding highlight that the benefit of FCM extends beyond short-term hemoglobin correction.

An important practical aspect demonstrated in this study was the number of visits required to complete therapy. Women receiving iron sucrose needed multiple infusion sessions, whereas most women receiving FCM completed treatment in one or two sittings. In routine clinical practice, especially in district-level hospitals and peripheral settings, fewer hospital visits directly support better compliance. For many pregnant women, travel, household responsibilities, and associated costs act as barriers to repeated treatment attendance. Therefore, the reduced visit burden with FCM is a meaningful advantage.

Regarding safety, both preparations were generally well tolerated. Mild infusion-related reactions were infrequent in both groups and required no specific interventions. However, the occurrence of symptomatic hypophosphatemia in a small proportion of women in the FCM group needs attention. Although these cases resolved without long-term consequences, the observation aligns with other reports indicating that FCM can temporarily alter phosphate handling. This does not negate the usefulness of FCM but suggests that awareness and monitoring are advisable when using higher doses or in women with repeated dosing needs.

Cost considerations need to be viewed in the context of total treatment delivery rather than the price of a single vial alone. While iron sucrose is cheaper per dose, the need for multiple hospital visits increases indirect costs and may also add to clinic load. On the other hand, FCM's higher per-dose cost may be offset by reduced visit frequency, shorter treatment duration, and higher likelihood of treatment completion. The economic balance may therefore differ across healthcare settings, and local factors such as drug procurement models and service capacity should guide therapy decisions.

The findings of this study align with several reports from tertiary and district healthcare centers across India and other regions, which have consistently shown faster correction of anemia with FCM. This consistency strengthens confidence in the advantages observed. However, the present study adds value by reflecting outcomes in a district-hospital environment, where patient flow, follow-up feasibility, and treatment accessibility differ from larger referral centers. Evidence from such settings is particularly relevant for programmatic planning in public health services.

This study has certain limitations. Follow-up was limited to four weeks after completion of therapy; therefore, longer-term hemoglobin stability and postpartum iron status could not be assessed. Additionally, the study lacked the power to identify minute variations in newborn outcomes, which require larger sample sizes. Despite these limitations, the study provides useful clinical and operational insights to guide selection of intravenous iron formulations in pregnancy. The results indicate that ferric carboxymaltose may be preferred when rapid correction and treatment completion are priorities, while iron sucrose remains a suitable option where cost constraints exist and compliance with multiple visits is manageable.

Conclusion

FCM and iron sucrose both increased this randomized comparative study examined the hemoglobin levels of pregnant women with IDA; however, FCM showed a larger and quicker rise in hemoglobin and ferritin concentrations, and the majority of participants finished therapy in fewer visits. This advantage is clinically relevant in settings where repeated hospital attendance may be difficult. Although treatment was generally well tolerated in both groups, a higher incidence of symptomatic hypophosphatemia was noted with FCM, indicating the need for appropriate monitoring in selected patients. Iron sucrose remained a safe and effective alternative, particularly where cost considerations and availability influence treatment decisions. Overall, FCM may be preferred when timely anemia correction and improved treatment adherence are priorities, while recognizing the importance of individual patient factors and resource context in guiding therapy selection.

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