

## ORIGINAL ARTICLE

## Evaluation of Ferric Carboxymaltose Versus Iron Sucrose Complex for the Treatment of Iron Deficiency Anemia During Pregnancy: A Non-Randomized Controlled Trial at a Single Tertiary Care Setting, Malir, Karachi

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### ABSTRACT

**Objective:** To assess and compare the efficacy of ferric carboxymaltose and iron sucrose complex in improving hemoglobin and serum ferritin levels among pregnant women diagnosed with iron deficiency anemia.

**Study Design:** Comparative interventional study using a quasi-experimental (non-randomized controlled trial) design.

**Place and Duration of Study:** This study was conducted at the Department of Obstetrics and Gynaecology, Combined Military Hospital (CMH), Malir, Karachi, from September 2024 to March 2025.

**Methods:** A total of 126 pregnant women with confirmed iron-deficiency anemia were allocated to two groups of 63 each. Group A received ferric carboxymaltose, while Group B received iron sucrose complex. Hemoglobin and serum ferritin levels were measured at baseline and again three weeks after treatment. Statistical evaluation was performed using SPSS version 26.

**Results:** In the ferric carboxymaltose group, the mean hemoglobin level rose from  $9.31 \pm 0.54$  g/dL at baseline to  $11.9 \pm 0.7$  g/dL after treatment. The iron sucrose complex group showed an increase from  $8.72 \pm 0.62$  g/dL to  $11.01 \pm 0.95$  g/dL. Both groups demonstrated statistically significant improvements ( $P < 0.001$ ), with ferric carboxymaltose showing a greater increase. Serum ferritin levels also rose significantly in both groups, with the ferric carboxymaltose group showing higher post-treatment values ( $P < 0.001$ ). Furthermore, 53 (42.1%) of patients in the ferric carboxymaltose group achieved haemoglobin levels above 12 g/dL, compared to just 10 (7.9%) in the iron sucrose complex group ( $P < 0.001$ ).

**Conclusion:** Ferric carboxymaltose was more effective than iron sucrose complex in improving both hemoglobin and serum ferritin levels among pregnant women with iron-deficiency anemia, suggesting it as a more potent therapeutic option.

**Keywords:** Anemia, Hemoglobin, Iron Sucrose.

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### Introduction

Iron deficiency anaemia is a common nutritional deficiency and a high-risk condition for pregnant women due to increased iron requirements during

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pregnancy.<sup>1,2</sup> Despite the general recommendation of oral iron therapy during pregnancy, poor patient adherence and side effects from the gastrointestinal absorption of iron tend to limit its effective administration.<sup>3,4</sup> In addition, oral therapy may not be adequate to treat moderate-to-severe anaemia, especially in the later stages of pregnancy.<sup>1,5</sup> These limitations can be overcome by prescribing parenteral iron therapy such as the iron sucrose complex. ISC is generally safe and does not require a test dose; however, it has some disadvantages, such as a limited dose per treatment and multiple visits, which increase overall cost. Several advantages have

made Ferric carboxymaltose (FCM), a dextran-free iron preparation method, desirable. FCM allows lower or higher doses to be administered in a shorter time, which facilitates more efficient replenishment of iron stores by releasing iron into the reticuloendothelial system.<sup>6,7</sup>

Multiple clinical studies have demonstrated how intravenous iron therapy helps patients overcome oral iron challenges when treating moderate-to-severe pregnancy-related anaemia. The prevalence of iron sucrose complex (ISC) as a parenteral iron therapy has increased because it offers safety advantages and minimal risk of severe hypersensitivity. The medication did not require a test dose before administration and was well-tolerated by patients. The administration of ISC requires multiple smaller doses across multiple healthcare visits, which leads to inconvenience for pregnant women and increased healthcare expenses. Current limitations have led researchers to investigate updated intravenous iron preparations that offer improved dosing and performance.<sup>2,8</sup>

Recently, ferric carboxymaltose has emerged as a new dextran-free parenteral iron formulation that delivers higher iron doses in a shorter infusion time. Its mechanism of action enables rapid, controlled release of iron into the reticuloendothelial system, thereby facilitating more efficient replenishment of iron stores. It is particularly suitable for pregnant women, as it may reduce hospital visits and accelerate the correction of anaemia. In terms of haemoglobin response and improvement in serum ferritin, FCM is promising compared with traditional iron formulations such as ISC. The introduction of FCM in clinical practice may shift treatment protocols, particularly in resource-constrained settings, where fewer hospital visits may reduce effort for both patients and healthcare systems. Multiple studies have confirmed the efficacy and safety of FCM, but this evidence should be supplemented by comparative effectiveness evaluations between FCM and ISC across several populations. This needs to be evaluated in a local context to guide clinical decisions and improve maternal outcomes. The purpose of this study was to fill this gap by evaluating the clinical efficacy of ferric carboxymaltose versus iron sucrose complex as the primary outcome measure for improving

haemoglobin levels in pregnant women with iron-deficiency anaemia.

## Methods

The study employed a comparative interventional design using a quasi-experimental (non-randomized controlled trial) approach and was conducted at the Department of Obstetrics and Gynecology, Combined Military Hospital (CMH) Malir, Karachi, Pakistan, from September 2024 to March 2025, following ethical approval from the hospital's Ethics Committee vide approval letter no: 109/2023/Trg/ERC, dated October 10, 2023. A total of 126 participants were recruited based on a calculated sample size, which accounted for anticipated proportions of patients achieving haemoglobin levels above 12 g/dL (22.5% for those receiving iron sucrose complex and 81.2% for those receiving ferric carboxymaltose), with a 95% confidence interval and a 10% absolute precision margin.<sup>8</sup>

Participants were selected through non-probability consecutive sampling. The study included pregnant women between 18 and 40 years of age, with gestational ages ranging from 16 to 36 weeks, who had iron deficiency anemia and hemoglobin levels between 6 and 10 g/dL. Women were excluded if their anemia was attributed to other causes, such as chronic infections (e.g., hepatitis or HIV), hemoglobin disorders (like thalassemia or sickle cell anemia), kidney dysfunction, elevated liver enzymes (more than 1.5 times the normal range), or if their serum creatinine exceeded 2.0 mg/dL. Those with known allergies to intravenous iron therapies were also excluded. Informed written consent was obtained from all participants prior to their inclusion in the study.

Participants were assigned to two equal groups (N=63 each) as per the obstetrician's discretion. Individual iron requirements were calculated using the Ganzoni formula, taking into account the patient's body weight and baseline haemoglobin concentration. Group A received intravenous ferric carboxymaltose (FCM), up to 1000 mg diluted in 200 mL of 0.9% saline, infused over 30 minutes. The dosage was rounded to the nearest 100 mg, and additional doses were given on days 7 and 14 if needed. Group B was treated with iron sucrose complex (ISC), receiving 300 mg doses diluted in 200 mL of saline, infused over 15–20 minutes, twice

weekly, with a maximum weekly dose of 600 mg. All participants also received standard supportive care, including deworming with mebendazole 100 mg twice daily for 3 days and a daily folic acid supplement (5 mg). If any participant experienced side effects such as rash, nausea, headache, abdominal discomfort, palpitations, injection site pain, or signs of anaphylaxis, they were withdrawn from the study and replaced to maintain the required sample size. Haemoglobin and serum ferritin levels were reassessed three weeks after therapy completion. The primary measure of treatment success was the number of patients with haemoglobin concentrations greater than 12 g/dL. Data were analyzed using SPSS version 26. Paired sample t-tests were applied to evaluate changes within each group, while independent sample t-tests and chi-square tests were used to compare outcomes between groups. A *P*-value ≤ 0.05 was considered significant.

**Results**

The mean age of the participants was 27.30 years (± 3.19), and the mean gestational age was 32.07 weeks (± 3.97). The participants had a mean parity of 2.25 (± 1.00) and a gravidity of 2.44 (± 1.07). Their mean body mass index was recorded at 26.05 kg/m<sup>2</sup> (± 3.54).

In the Ferric Carboxymaltose group, the mean initial hemoglobin concentration was 9.31 g/dL (± 0.54), which significantly increased to 11.9 g/dL (± 0.7)

after three weeks. A paired-samples t-test confirmed that the increase was statistically significant, *t* (62) = -41.01, *P* < .001. Similarly, the mean serum ferritin level rose from 10.71 ng/mL (± 4.55) at baseline to 20.01 ng/mL (± 4.95), a significant difference, *t* (62) = -58.10, *P* < .001.

In contrast, the Iron Sucrose Complex group had a baseline Hb level of 8.72 g/dL (± 0.62), which increased to 11.01 g/dL (± 0.95) after three weeks. This change was statistically significant, *t* (62) = -30.27, *P* < .001. The mean serum ferritin level in the ISC group increased from 11.83 ng/mL (± 5.2) to 15.94 ng/mL (± 5.84), reflecting a significant difference, *t* (62) = -35.03, *P* < .001.

An independent-samples t-test revealed a significant difference in hemoglobin levels at the three-week mark between the FCM and ISC groups, *t* (113.75) = 6.007, *P* < .001. A similar test of serum ferritin levels also showed a significant difference between groups at three weeks, *t* (120.69) = 4.22, *P* < .001 (Table 1).

When evaluating the proportion of patients achieving hemoglobin levels above 12 g/dL, 10 of 63 patients (8%) in the ISC group met this target, compared with 42 of 62 patients (33.6%) in the FCM group. Overall, 52 of 125 participants (41.6%) attained Hb >12 g/dL, whereas 73 (58.4%) did not. A chi-square test showed a significant association between the type of intravenous iron used and achieving Hb >12 g/dL ( $\chi^2$  (1) = 35.46, *P* < .001 (Table 2).

**Table 1: Comparison of hemoglobin and serum ferritin levels between ISC and FCM groups at baseline and after 3 weeks**

Parameter	Group	Mean ± Std.	t-test	P-value
Baseline Hb level	ISC	8.72 ± 0.62	-	-
	FCM	9.31 ± 0.54		
Hb level 3 weeks	ISC	11.01 ± 0.95	6.007	<.001
	FCM	11.90 ± 0.70		
Serum Ferritin Baseline Level	ISC	11.83 ± 5.2	-	-
	FCM	10.71 ± 4.55		
Serum Ferritin level 3 weeks	ISC	15.94 ± 5.84	4.22	<.001
	FCM	20.01 ± 4.95		

**Table 2: Association between IV iron formula and achievement of hemoglobin >12 g/dL**

		IV Iron formula given						Chi-Square	P-value
		ISC		FCM		Total			
		N	%	N	%	N	%		
Hb >12 achieved	No	53	42.1%	20	15.9%	73	58.4%	35.46	< .001
	Yes	10	7.9%	43	34.1%	53	41.6%		
	Total	63	50%	63	49%	126	100%		

## Discussion

This study compared ferric carboxymaltose (FCM) and iron sucrose complex (ISC) for the management of iron-deficiency anaemia (IDA) during pregnancy and found that FCM resulted in a much greater increase in haemoglobin (Hb) and serum ferritin levels after 3 weeks of treatment. These results align with an emerging body of evidence indicating that FCM is faster and more effective for iron repletion than traditional formulations.

In the current literature, various studies have shown that FCM is superior to other methods in improving haematological parameters. In a meta-analysis, Shin HW et al. found that FCM increased Hb by approximately 0.6-0.7 g/dL compared with ISC and serum ferritin at follow-up.<sup>9</sup> Bharadwaj MK et al. reviewed 22 studies and found similar results, with patients who received FCM exhibiting higher ferritin restoration and reduced infusion-related adverse events.<sup>10</sup> These trends were also observed in regional statistics. According to Agrawal and Masand, the mean Hb level in the FCM group improved by 2.9 g/dL compared to the ISC group by 1.1 g/dL in pregnant women.<sup>11</sup> Khatun and Biswas demonstrated a 2.68 g/dL increase in Hb with FCM versus 1.97 g/dL with ISC in three weeks.<sup>12</sup> Lunagariya M et al. and Chaudhary also reported similar results in India, where FCM had a higher proportion of women with Hb above 11 g/dL in a shorter period.<sup>13,14</sup>

The results of this study are also consistent with the published data in Pakistan. Jamal H et al. found that Hb increased by 3.18 g/dL with FCM versus 2.14 g/dL with ISC in antenatal women in Faisalabad.<sup>15</sup> Chughtai F et al. found that in Rawalpindi, the FCM group increased by 3.96 g/dL on average as compared to 2.11 g/dL in the ISC group.<sup>16</sup> Wajid R et

al. also found that 81 per cent of women receiving FCM had an Hb level over 12 g/dL versus 22 per cent in the ISC group.<sup>8</sup> These trends were recently validated by Sattar S et al., who found a mean Hb of 10.8 g/dL in the FCM group and 10.2 g/dL in the ISC group, with 94 per cent of FCM recipients denying any side effects.<sup>17</sup> The external validity of our findings is supported by the consistency of the results obtained at various centres in Pakistan. This indicates that FCM is a powerful and well-tolerated agent for managing IDA during pregnancy.

The physiological mechanisms that make FCM better than other iron supplements are its molecular structure, which enables regulated release of iron to the reticuloendothelial system without the formation of free radicals that lead to oxidative stress. This process allows high single doses of up to 1000 mg to be administered in a brief infusion, replenishing iron stores more rapidly than the numerous smaller infusions needed for ISC.<sup>6</sup> This corresponded to improved Hb and ferritin recovery and reduced the number of visits required in our cohort, which is essential for pregnant women who might have logistical and financial constraints to attend the hospital repeatedly.

Economic factors are still being debated. However, the unit price of FCM is higher than that of ISC, but overall treatment costs might not differ significantly when reduced administration schedules and indirect costs are considered.<sup>18,19</sup> FCM is cost-effective in high-volume hospitals because of its shorter administration schedule and lower indirect costs. These results indicate that implementing FCM can reduce congestion in existing public healthcare centres in Pakistan, where antenatal clinics are already overcrowded. A few comparative studies

using equalised total iron doses have shown similar final Hb levels between the two formulations. According to Bharadwaj MK et al. standardising cumulative iron exposure and the follow-up period makes Hb correction more similar; however, FCM offers compliance and convenience advantages.<sup>10</sup> This difference may be explained by differences in dosing schedules, baseline anaemia severity, and monitoring intervals. The short follow-up period in our study may have contributed to lower ferritin increments than in longer trials. Such variability suggests that, although FCM is generally more effective, both agents are effective, and the choice may be influenced by the clinic's situation, urgency, and available resources. These results have practical implications for Pakistan. Iron-deficiency anaemia occurs in over 50 percent of pregnant women, most commonly late in pregnancy, when there is little time to rectify it.<sup>20</sup> The ability of FCM to rapidly replenish iron is appropriate in such situations. The FCM minimises the risk of insufficient therapy due to missed appointments, which are common in resource-constrained areas, by administering the full dose in fewer sessions. Fewer visits also reduce out-of-pocket expenses, such as transport costs and time wasted on work or domestic chores. Therefore, FCM can increase compliance and improve antenatal outcomes in groups with limited access to continuous care. This study adds to the local evidence base by providing information on a tertiary military hospital serving both urban and peri-urban communities. The findings of this study demonstrate that FCM not only improves laboratory markers but also benefits operations by reducing patient load and turnover in infusion rooms. Our results complement the regional data on the broader use of FCM in Pakistan in women with moderate-to-severe anaemia in whom oral therapy is insufficient. The results have several limitations that should be considered when interpreting them. The research was not randomised, which raises the possibility of selection bias, as group allocation was not random but at the discretion of the clinicians. Age, gestational age, and baseline Hb levels were similar, indicating they could be compared, but confounding factors may still have been unmeasured. This was a single-center study, which limits extrinsic generalisability because other healthcare facilities

might have different treatment regimens and demographics. The three-week follow-up period showed only early haematologic response, not long-term iron repletion or post-delivery outcomes. No maternal or neonatal outcomes (preterm birth, birth weight, or postpartum haemorrhage) were documented, which restricts the inferences to clinical outcomes other than laboratory values. Despite these limitations, the findings provide practical guidance for practice and research. These findings require large multicentre randomised controlled trials in Pakistan to confirm them and eliminate confounding factors. The persistence of Hb improvement and its association with maternal and neonatal outcomes should be determined through extended follow-up. A comparative study of the total treatment costs, including staff time and hospital resources, would shed light on the economic feasibility of an institutional-level switch between ISC and FCM. Barriers to treatment completion can also be determined by investigating patient satisfaction, adherence, and perceptions. Future studies on the use of FCM in special cases, such as twin pregnancies, pre-eclampsia, or women with chronic inflammatory diseases, can further increase its clinical applicability. Comparative research on the management of postpartum or early puerperal anaemia might help determine whether early correction using FCM affects recovery and lactation performance. The addition of biomarkers such as hepcidin and transferrin saturation in subsequent research would provide more mechanistic support for the accelerated iron use by FCM.

## Conclusion

Ferric carboxymaltose was assessed for the treatment of iron-deficiency anaemia in pregnant women and was found to be superior to the iron sucrose complex in both the speed and magnitude of improvement in haemoglobin concentration. Both treatments improved serum ferritin levels, but the proportion of patients who achieved the target haemoglobin level was higher with FCM, which was particularly suitable for moderate-to-severe anaemia or late pregnancy. FCM offers clear clinical advantages over other methods of rapid anaemia correction in antenatal care and should be considered a preferred option in resource-limited settings, despite cost considerations.

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**Author Contributions**

**AK:** Conception, design of the work, and approval for final submission

**BI:** Manuscript writing for methodology design, investigation, and approval for final submission

**MS:** Revising, editing, supervising for intellectual content, and approval for final submission

**JA:** Data acquisition, curation, statistical analysis, and approval for final submission

**RK:** Writing the original draft, proofreading, and approval for final submission

**SN:** Validation of data, interpretation, write-up of results, and approval for final submission

**AK is the nominated guarantor and takes full responsibility for the overall content and integrity of the work**

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