Original Article

# Comparison of Iron Sucrose Complex Versus Ferric Carboxymaltose for Establishment of Effective Breastfeeding: A Quasi-Experimental Study

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## Abstract

Objectives: To compare iron sucrose complex (ISC) versus ferric carboxymaltose (FCM) for establishment of effective breastfeeding
Methodology: This quasi-experimental study was conducted at Sir Ganga Ram Hospital Lahore from January to April 2025. Total 70 pregnant women with moderate-severe iron deficiency anemia were assigned, without randomization, into two equal size groups i.e. ISC and FCM. Baseline data were collected upon enrollment and outcome data at day-21 after intervention. Mann-Whitney U test used for comparing median (IQR), and Chi square test for frequency (percentage) between ISC and FCM groups. Linear regression analyses performed for neonatal weight gain and lactation initiation time; and multivariate binary logistic regression analyses for lactation adequacy.
Results: The distribution of baseline demographic and obstetric characteristics across study groups was equivalent (all p >0.05). At the day-21 follow-up, the ISC group, compared to the FCM group, showed less improvement in hemoglobin levels (0.8 vs. 1.9 g/dL, p <0.001) and serum ferritin (19.0 vs. 21.5 ng/mL, p 0.780). The ISC group also experienced a longer time to initiate breastfeeding (20 vs. 9 hours, p <0.001), but demonstrated higher lactation sufficiency (59.0% vs. 41.0%, p 0.072) and greater neonatal weight gain (680 vs. 31 grams, p <0.001). Being in FCM group showed negative association with neonatal weight gain (β -321.251, p <0.001) early breastfeeding initiation (β -8.396, p 0.004) and greater risk of lactation insufficiency (aOR 5.593, p 0.050).
Conclusion: Both ISC and FCM treatments offer unique benefits. FCM was better at improving maternal hemoglobin levels, while ISC showed advantages in terms of neonatal growth and early breastfeeding initiation. Therefore, selection of treatment should consider both maternal hematologic goals and neonatal well-being.
Keywords: Breastfeeding, Ferric carboxymaltose, Iron sucrose, Pregnancy.

Cite this article as: Malik A, Janjua M, Shahzad Q, Sattar Y. Comparison of Iron Sucrose Complex Versus Ferric Carboxymaltose for Establishment of Effective Breastfeeding: A Quasi-Experimental Study. J Soc Obstet Gynaecol Pak. 2025;15(3): 185-190. DOI. 10.71104/jsogp.v15i3.936

## Introduction

Breastfeeding is widely recognized for its significant health benefits for both mother and child, contributing to optimal growth, development, and immune protection in infants.[1] Iron deficiency anemia (IDA) during pregnancy and postpartum periods can impede breastfeeding outcomes, making effective iron supplementation crucial.[2] The World Health Organization (WHO) estimates that 36.5% of pregnant women globally suffer from anemia, which adversely impacts maternal recovery, lactation, and neonatal health.[3] In Pakistan, IDA affects approximately 45% of pregnant women, representing a significant public health concern.[4] Oral iron supplementation is the first line of treatment for IDA. However, its gastrointestinal side effects and slow onset of action often lead to poor compliance and limited efficacy in late pregnancy.[5] Intravenous (IV) iron therapies, such as ferric carboxymaltose (FCM) and iron sucrose (IS), provide rapid replenishment of iron stores

Authorship Contribution: [1]Conception, design, critical review, approve and responsible for the article, [2]Conception, design, data entry and analysis, article draft writing, approve and responsible for the article. [3]Data acquisition and interpretation, article draft writing, critical review, approve and responsible for the article. [4]Data acquisition and interpretation, critical review, approve and responsible for the article.

Funding Source: none
Conflict of Interest: none

Received: May 16, 2025
Revised: June 30, 2025
Accepted: July 12, 2025

with fewer adverse effects.[6,7] FCM, in particular, demonstrates a higher increase in hemoglobin (Hb) and ferritin levels compared to IS, along with fewer side effects. Nonetheless, the side effects of FCM require more comprehensive analysis to conclusively establish its superiority in treating iron deficiency anemia (IDA) during pregnancy.[8] Although IV iron therapy during pregnancy enhances hematological parameters, there is no evidence to suggest improvements in critical maternal or perinatal outcomes. No single IV iron formulation has proven to be superior, and the choice of IV iron preparation is typically based on cost and ease of administration.[9] While these studies primarily focus on hematological outcomes, it is also crucial to understand the implications of iron sucrose complex (ISC) and FCM on breastfeeding. Given the vital role of maternal iron status in lactation, further research is necessary to elucidate how these treatments affect breastfeeding practices and outcomes. Therefore, the study aimed to compare iron sucrose complex versus ferric carboxymaltose for establishment of effective breastfeeding. This study will provide evidence on the optimal management of IDA in pregnancy to improve maternal recovery, lactation outcomes, and neonatal health while minimizing costs and adverse effects.

## Methodology

A quasi-experimental study with two group pre-and post-test design was conducted at a public tertiary care Sir Ganga Ram Hospital Lahore from January to April 2025. Pregnant women diagnosed with moderate to severe IDA were enrolled by purposive sampling method. IDA defined as hemoglobin level 6.0-10.0 g/dL, reduced RBC indices (MCV <27 fL & MCH <32 pg), and low ferritin level (<30 ng/mL). Other inclusion criteria were age 18-40 years, gestation age 29-36 weeks, singleton, any gravida and parity status. Exclusion criteria were women with chronic infections (hepatitis & AIDS), serum creatinine >2.0 mg/dL, and known hypersensitivity to IV iron therapies.

The study adhere to the Declaration of Helsinki and approved by the hospital committee vide letter No.87/CIERB dated 16 January 2025. Written informed consent sought from all volunteer participants ensuring confidentiality and the right to withdraw at any time.

Minimum sample size for each group was determined using mean difference in Hb level between the groups at day 21,[10] 99.0% confidence interval and 95.0% power of test by OpenEpi version 3 calculator. Out of total 110 women assessed for eligibility, 70 women met the selection criteria and allocated to two equal-sized intervention groups. Details are shown in flow diagram as Figure 1.

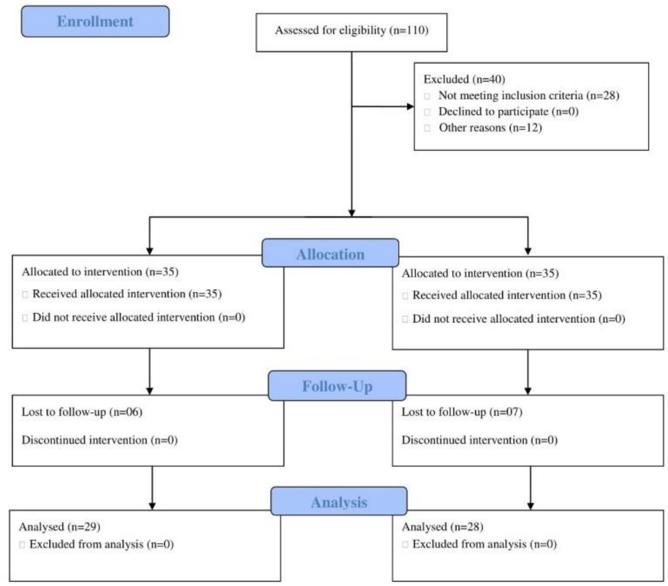


**Figure 1. CONSORT flow diagram for quasi experiment.**

All eligible women were assigned, without randomization, into two equal size independent intervention groups i.e. ISC and FCM. Total iron dose was calculated using the following formula:

$$2.4 \times \text{Body Weight (kg)} \times (\text{Target Hb} - \text{Actual Hb}) + 500 \text{ mg (iron stores)}$$

In ISC group, women received IV Iron Sucrose 200 mg in 250 mL saline infused over 1 hour, thrice weekly until the calculated dose reached. In FCM group, women received IV Ferric Carboxymaltose in doses of up to 1000 mg weekly, in 100 mL saline, infused over 15 minutes. The maximum cumulative dose did not exceed 2500 mg. Age, gestational age, gravida, para, abortus, education status, employment status, household income, hemoglobin level, and serum ferritin level were recorded at the time of enrollment in the study.

Establishment of effective breastfeeding in terms of lactation adequacy and neonatal weight gain on day 21 postpartum and breastfeeding initiation time were assessed. Effective breastfeeding defined as successful lactation initiation by day 21 postpartum, defined by adequate maternal milk production and neonatal weight gain. The infant is receiving only breast milk (no formula, water, or other feeds) as per WHO and UNICEF guidelines for exclusive breastfeeding initiation. The baby regains birth weight by day 10 and shows a weight gain of 20–30 grams per day thereafter, indicating sufficient milk intake. At least 6–8 wet diapers and 3–4 stools per day by day 21 postpartum, reflecting adequate milk transfer. Change in hemoglobin and ferritin levels were also assessed on day 21 postpartum.

Statistical Package for Social Sciences (SPSS) version 26 used for data analysis. After normality assessment by Shapiro-Wilk test, median (interquartile range (IQR)) calculated for continuous variables. Frequency (percentage) calculated for categorical variables. Mann-Whitney U test used for comparing median (IQR), and Chi square test for frequency (percentage) between ISC and FCM groups. Linear regression analyses performed for neonatal weight gain and lactation initiation time; and multivariate binary logistic regression analyses for lactation adequacy. P-value ≤0.05 considered as significant.

## Results

Table I demonstrate that the distribution of baseline demographic and obstetric characteristics across study groups was equivalent (all p >0.05).

Table II shows that baseline hemoglobin levels and calculated iron doses were comparable between the two study groups. However, the baseline ferritin level was significantly higher in the ISC group than in the FCM group (16.0 vs. 10.0 ng/mL, p = 0.007). The ISC group also received a significantly higher administered dose of iron (600 vs. 500 mg, p = 0.014) and a greater number of infusions (3.0 vs. 1.0, p < 0.001).

At the day-21 follow-up, the ISC group, compared to the FCM group, showed less improvement in hemoglobin levels (0.8 vs. 1.9 g/dL, p <0.001) and serum ferritin (19.0 vs. 21.5 ng/mL, p 0.780). The ISC group also experienced a longer time to initiate breastfeeding (20 vs. 9 hours, p <0.001), but demonstrated higher lactation sufficiency (59.0% vs. 41.0%, p 0.072) and greater neonatal weight gain (680 vs. 31 grams, p <0.001).

Regression analysis in Table 3 shows that being in FCM group (β -321.251, p <0.001) and unit increase in Hb (β -148.720, p <0.001) and gestational age (β -21.837, p 0.019) were negatively associated with neonatal weight gain. Being in FCM group also showed negative

**Table I: Baseline characteristics of study groups.**

| | | Total (n=57) | ISC (n=29) | FCM (n=28) | p-value |
|---|---|---|---|---|---|
| Age (years) | | 25.0 (7.0) | 24.0 (8.0) | 25.0 (5.0) | 0.706* |
| Household income (PKR/month) | | 30000.0 (20000.0) | 30000.0 (20000.0) | 30000.0 (31000.0) | 0.841* |
| Education status | Illiterate | 07 (100.0%) | 04 (57.1%) | 03 (42.9%) | 0.899** |
| | Primary | 05 (100.0%) | 03 (60.0%) | 02 (40.0%) | |
| | Middle | 08 (100.0%) | 05 (62.5%) | 03 (37.5%) | |
| | Matric | 24 (100.0%) | 11 (45.8%) | 13 (54.2%) | |
| | Graduate | 13 (100.0%) | 06 (46.2) | 07 (53.8%) | |
| Place of residence | Urban | 49 (100.0%) | 24 (49.0%) | 25 (51.0%) | 0.706** |
| | Rural | 08 (100.0%) | 05 (62.5%) | 03 (37.5%) | |
| Employment status | Housewife | 47 (100.0%) | 25 (53.2%) | 22 (46.8%) | 0.504** |
| | Working | 10 (100.0%) | 04 (40.0%) | 06 (60.0%) | |
| Gestational age (weeks) | | 32.0 (4.0) | 31.0 (4.0) | 33.0 (5.0) | 0.061* |
| Gravida | | 2.0 (2.0) | 3.0 (2.0) | 2.0 (2.0) | 0.397* |
| Para | | 1.0 (2.0) | 1.0 (2.0) | 1.0 (3.0) | 0.491* |
| Miscarriage | | 0.0 (0.0) | 0.0 (1.0) | 0.0 (0.0) | 0.574* |

*Mann-Whitney U test; **Pearson Chi square test

**Table II: Comparison of iron profiles and effective breastfeeding between study groups.**

| | | Total (n=57) | ISC (n=29) | FCM (n=28) | p-value |
|---|---|---|---|---|---|
| Baseline hemoglobin level (g/dl) | | 8.7 (1.0) | 8.8 (0.8) | 8.6 (1.1) | 0.122* |
| Baseline ferritin level (ng/ml) | | 12.0 (12.0) | 16.0 (8.0) | 10.0 (10.0) | 0.007* |
| Iron dose calculated | | 910.0 (226.0) | 917.0 (224.0) | 857.0 (252.0) | 0.362* |
| Iron dose administered | | 600.0 (100.0) | 600.0 (100.0) | 500.0 (0.0) | 0.014* |
| Number of infusions | | 2.0 (2.0) | 3.0 (1.0) | 1.0 (0.0) | <0.001* |
| Postpartum hemoglobin level (g/dl) | | 9.7 (1.0) | 9.5 (0.7) | 10.0 (1.4) | <0.001* |
| Postpartum ferritin level (ng/ml) | | 31.0 (13.0) | 33.0 (17.0) | 30.0 (9.0) | 0.080* |
| Change in hemoglobin level (g/dl) | | 1.1 (1.2) | 0.8 (0.4) | 1.9 (0.8) | <0.001* |
| Change in ferritin level (ng/ml) | | 19.0 (14.0) | 19.0 (18.0) | 21.5 (15.0) | 0.780* |
| Neonatal weight gain (grams) | | 543.0 (664.0) | 680.0 (155.0) | 31.0 (14.0) | <0.001* |
| Breastfeeding initiation time (hours) | | 12.0 (16.0) | 20.0 (16.0) | 9.0 (12.0) | <0.001* |
| Lactation adequacy | Sufficient | 39 (100.0%) | 23 (59.0%) | 16 (41.0%) | 0.072** |
| | Insufficient | 18 (100.0%) | 06 (33.3%) | 12 (66.7%) | |

*Mann-Whitney U test; **Pearson Chi square test association with breastfeeding initiation time (β -8.396, p 0.004) and greater risk of lactation insufficiency (aOR 5.593, p 0.050).

## Discussion

Adequate maternal iron levels are essential for the synthesis of iron-dependent enzymes and proteins that support milk production, particularly those involved in the metabolic processes of the mammary glands. Iron also plays a vital role in maintaining the maternal energy, and a deficiency can lead to fatigue that may affect her ability to breastfeed regularly and care for her infant. Moreover, iron supports immune function, and insufficient levels may weaken the immune-enhancing properties of breast milk or increase the mother's vulnerability to infections that could disrupt breastfeeding.

IDA is a significant public health concern during pregnancy and the postpartum period, affecting both maternal and neonatal health.[11] Iron therapy is widely used to replenish iron levels, benefiting the well-being of both mother and newborn.[12] Intravenous ISC has traditionally been the standard IRT; however, its use is limited by certain side effects. In contrast, FCM has emerged as a promising alternative, providing effective iron replenishment with minimal adverse effects.[6–8] Additionally, FCM therapy is significantly more cost-effective than ISC treatment.[13] As research continues to support the safety and efficacy of FCM, its role in managing postpartum IDA becomes increasingly valuable in improving maternal and neonatal outcomes.

Studies have demonstrated the rapid effects of iron therapy, whether through ISC or FCM, on hemoglobin (Hb) and iron levels.[6–8] However, no direct link has been established between iron therapy and lactation adequacy, breastfeeding duration, or neonatal weight gain. Nevertheless, FCM has been found to increase breast milk iron concentrations in mothers with IDA.[14] Maternal iron status can influence overall health and energy levels, potentially affecting breastfeeding duration. The present study evaluated the impact of FCM versus standard ISC treatment on the establishment of effective breastfeeding in pregnant women with moderate-to-severe IDA. While no significant difference was observed in lactation adequacy between the two groups, FCM-treated mothers initiated breastfeeding earlier but exhibited lower neonatal weight gain compared to ISC-treated women.

**Table III: Impact of maternal factors and iron therapy on effective breastfeeding.**

| | Model 1 | | | Model 2 | | | Model 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| **Neonatal weight gain** | | | | | | | | | |
| | **β** | **SE** | **p-value** | **β** | **SE** | **p-value** | **β** | **SE** | **p-value** |
| IRT (ISC/FCM) | -498.532 | 48.376 | <0.001 | -339.475 | 55.32 | <0.001 | -321.251 | 52.990 | <0.001 |
| Change in Hb level | | | | -153.737 | 34.943 | <0.001 | -148.720 | 33.378 | <0.001 |
| Age (years) | | | | | | | -6.694 | 5.098 | 0.195 |
| Gestational age (weeks) | | | | | | | -21.837 | 9.034 | 0.019 |
| Para | | | | | | | 4.728 | 18.699 | 0.801 |
| **Breastfeeding initiation time** | | | | | | | | | |
| | **β** | **SE** | **p-value** | **β** | **SE** | **p-value** | **β** | **SE** | **p-value** |
| IRT (ISC/FCM) | -8.637 | 2.031 | <0.001 | -8.702 | 2.708 | 0.002 | -8.396 | 2.783 | 0.004 |
| Change in Hb level | | | | 0.064 | 1.710 | 0.970 | 0.252 | 1.753 | 0.886 |
| Age (years) | | | | | | | 0.136 | 0.268 | 0.614 |
| Gestational age (weeks) | | | | | | | -0.454 | 0.475 | 0.343 |
| Para | | | | | | | -0.187 | 0.982 | 0.850 |
| **Lactation adequacy (sufficient/insufficient)** | | | | | | | | | |
| | **OR** | **95% CI** | **p-value** | **OR** | **95% CI** | **p-value** | **OR** | **95% CI** | **p-value** |
| IRT (ISC/FCM) | 2.875 | 0.893-9.258 | 0.077 | 6.162 | 1.082-35.086 | 0.040 | 5.593 | 0.997-31.363 | 0.050 |
| Change in Hb level (≥1.0/<1.0) | | | | 3.101 | 0.552-17.413 | 0.199 | 2.579 | 0.443-14.995 | 0.292 |
| Age (≤25/>25 years) | | | | | | | 0.748 | 0.198-2.827 | 0.668 |
| Gestational age (≤32/>32 weeks) | | | | | | | 0.902 | 0.265-3.070 | 0.868 |
| Para (≤2/>2) | | | | | | | 0.643 | 0.128-3.226 | 0.592 |

IRT: Iron replacement therapy; ISC: Iron sucrose complex; FCM: Ferric carboxymaltose; Hb: Hemoglobin; β: Unstandardized coefficient; SE: Standard error

Seid et al. reported that mothers treated with intravenous FCM achieved a rapid Hb increase of ≥3 g/dL and attained Hb levels above 12 g/dL in a shorter time compared to those receiving oral ferrous sulfate.[15] Similarly, Jose et al. found that the mean Hb increase in the FCM group (29 g/L) was significantly higher than in the ISC group (22 g/L) after three months ($p < 0.001$).[16] Shah et al. observed a mean Hb increase of 2.52 g/dL in the FCM group and 2.35 g/dL in the ISC group ($p < 0.001$).[17] Naqash et al. reported a significant rise in mean Hb levels, from 7.76 to 13.25 g/dL in FCM-treated patients and from 7.64 to 11.59 g/dL in ISC-treated patients, one month post-therapy ($p < 0.001$).[18] Likewise, the present study showed a significant rise in median Hb levels, from 8.6 to 10.0 g/dL in FCM-treated women and from 8.8 to 9.5 g/dL in ISC-treated women, by day 21 post-therapy ($p < 0.001$).

Regarding iron storage indicators, Naqash et al. reported a significant increase in serum ferritin levels, rising from 8.32 to 38.94 μg/L in FCM-treated patients and from 8.16 to 27.0 μg/L in ISC-treated patients after one month of therapy ($p < 0.001$).[18] Conversely, Patel et al. observed an increase in serum ferritin levels in both therapies at days 8 and 15, but the difference was not statistically significant in pregnant or postpartum women.[19] Similarly, the present study noted an increase in serum ferritin levels from 10.0 to 30.0 ng/mL in FCM-treated women and from 16.0 to 33.0 ng/mL in ISC-treated women at day 21 post-therapy, though the difference between the two treatments was not statistically significant ($p = 0.080$). These findings indicate that the results of the present study align with existing literature. Though, the study has certain limitations, such as its quasi-experimental design, which may affect the ability to establish causal relationships. Additionally, the lack of randomization could introduce selection bias, and its single-center setting and relatively small sample size may limit the generalizability of the findings to broader populations.

## Conclusion

In conclusion, both ISC and FCM treatments offer unique benefits. FCM was better at improving maternal hemoglobin levels, while ISC showed advantages in terms of neonatal growth and early breastfeeding initiation. Therefore, selection of treatment should consider both maternal hematologic goals and neonatal well-being. More research is needed to confirm these results and explore their long-term effects.

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