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Indian Journal of Obstetrics and Gynecology Research

Journal homepage: www.ijogr.org

Original Research Article

A comparative study of iron isomaltoside versus iron sucrose in treating anemia in postpartum

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Abstract

Background: The most frequent hematological disorder identified during pregnancy is anemia. The World Health Organization defines anemia during pregnancy as having a hemocrit of less than 33% and a hemoglobin content of less than 11 grams per milliliter. This study aimed to examine the safety, effectiveness, of intravenous iron isomaltoside versus intravenous Iron sucrose in the treatment of postpartum anemia.

Materials and Methods: This Randomised parallel group trial study will be done in the Department of Obstretrics and Gynaecology Shri B. M. Patil Medical College Hospital and Research Centre. All postpartum women between day 1 and day 10 of normal delivery or cesarean section with moderate anaemia (Hb 7-11 gm/dl) admitted in labor room and wards and agreeing to give written and informed consent will be included in the study.

Then subjects will be randomized in to two groups in 1:1, 108 subjects in each group Group 1: One gram of intravenous iron isomaltoside was administered in a single dosage. Group 2: 200 mg, 200 mg, and 200 mg of iron sucrose were given intravenously for three days totaling 600 mg.

Then the CBC and serum ferritin levels will be checked on the recruitment day followed by 21st day after therapy.

Result: The Hb increase experienced by women in the iron isomaltoside group was 1.4 gm more than that of the iron sucrose group, and this difference was statistically significant (P value <0.001). The mean size of Hb was likewise large, coming in at 2.086 mg for the iron isomaltoside group and 1.766 gm for the iron sucrose group. Both groups had an increase in serum ferritin, a measure of their iron storage.

Conclusion: Iron isomaltoside is an efficient alternative to Iron Sucrose in treating postpartum anemia. It has an added advantage of single dose regime and lower incidence of side effects.

Keywords: Iron isomaltoside, Iron sucrose, Postpartum anemia, Anemia, Anemia in puerperium.

Received: 16-09-2024; **Accepted:** 18-10-2024; **Available Online**: 28-05-2025

1. Introduction

The most frequent haematological problem identified during pregnancy is anemia. The World Health Organization defines anemia during pregnancy as having a hemocrit of less than 33% and a hemoglobin content of less than 11 grams per milliliter.[1]

Anemia was defined by the centers for disease control and prevention in 1990 as hemoglobin less than 10 gm/dl in the first and third trimesters and less than 10.5 gm/dl in the second trimester.[2]

Whereas ICMR (The Indian Council of Medical Research) categorize, anaemia in four categories, which are;

Table 1: ICMR classification of anemia

Category	Anaemia severity	Hb level in gm/dl
1	Mild	10-10.9
2	Moderate	7.9-9
3	Severe	4-6.9
4	Very severe	<4

Serum ferritin of less than 15 µg/l and hemoglobin of less than 10gm/dl within 24 to 48 hours following delivery are considered as postpartum anemia. Compared to wealthy nations, the prevalence of anemia related to pregnancy in underdeveloped nations like India might reach 50–80%. The most common type of anemia that develops during pregnancy

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https://doi.org/10.18231/j.ijogr.2025.047

and puerpurium is dimorphic anemia, which is caused by a single or combined nutritional shortage of iron, vitamin B12, and folic acid. Other factors that contribute to such a wide disparity in statistics include third-trimester anemia due to low intake of essential nutrients, a mostly vegetarian diet, and frequent pregnancies at short intervals, and chronic blood loss from infections like malaria and hookworm infestation.[3]

Erythropoiesis requires sufficient quantities of erythropoietin, iron, folic acid, vitamin B12, vitamin C, trace amounts of zinc, and amino acids. Pregnancy boosts the body's requirement for iron. The average maternal iron requirement for a singleton gestation is 1000 mg. Of these, the fetus and placenta require 300 mg, the mother's hemoglobin mass expansion requires 500 mg, and the skin, urine, and stomach generally excrete 200 mg.[4] If iron supplementation is not administered, the cumulative need of 1000 mg surpasses the iron store of the majority of women and causes iron deficiency anemia.

Throughout India, the National Nutritional Anaemia Control Programme (NNACP), which was founded in 1970, is carried out through primary health centers and subcenters. It was suggested that pregnant moms take one iron pill every day for at least 100 days after the first trimester of pregnancy. Each tablet includes 60mg of elemental iron and 500 mcg of folic acid. For women who are nursing, the same dosage applies. Iron deficiency anemia (IDA) is still quite common in pregnant and postpartum women, even with the NNACP's tireless efforts.[5]

Iron therapy is the only treatment for iron deficiency anemia, aside from the dietary changes already discussed. Government programs for the prevention and treatment of anemia use oral iron since it is a cost-efficient, safe, and effective means to replace iron. Typically, vitamin C and 180–200 mg of elemental iron are administered in two or three separate doses, spaced between meals.[6]

When oral therapy is inadequate and fast iron supply is clinically necessary, intravenous ferric derisomaltose/iron isomaltoside 1000 (FDI) treatment (Monofer®/Monoferric®, Pharmacosmos, Holbaek) is recommended.[7] FDI is among the newest IV iron formulations available on the market. It is made up of a carbohydrate moiety and iron that is firmly coupled in a matrix structure. It was first introduced in Europe in 2010. The matrix structure permits a controlled and progressive transfer of iron to iron-binding proteins, therefore averting potential toxicity from the release of labile iron. FDI has been studied in non-clinical reprotoxicology experiments. Prenatal defects in rabbits were treated with supratherapeutic dosages. [Brochure for Monofer® Investigators].

At the suggested therapeutic dose, there is thought to be little chance of teratogenic or fetotoxic consequences. Unexpected safety risks have not been found in any of the few published trials on the use of FDI to treat iron deficient anemia. FDI should only be used in the second and third trimesters of pregnancy if the benefits are shown to outweigh any potential risks to the mother and the fetus.

In November 2000, the FDA authorized iron sucrose (IS). Iron hydroxide sucrose compound in water is known as iron sucrose. Iron sucrose has a molecular weight of 34,000-60,000 Daltons. Iron sucrose can be infused intravenously as a brief infusion over 20–30 minutes in 100 ml of normal saline or as a bolus injection over 5–10 minutes. A test dosage is not necessary. A 200 mg maximum daily bolus dosage can be administered one at a time, no more than three times per week. Local discomfort, nausea, disorientation, and a metallic taste are common adverse effects.[8]

2. Aims and Objectives of Study

1. To prove, parenteral iron treatment is a safe and efficient method of treating iron deficient anemia.
2. To compare efficacy, safety of intravenous iron sucrose v/s Intravenous isomaltoside.
3. To compare cost effectiveness of intravenous iron sucrose v/s intravenous isomaltoside.

3. Materials and Methods

This Randomised parallel group trial study will be done in the Department of Obstretics and Gynaecology B.L.D.E (DU) Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka. All postpartum women between day 1 and day 10 of normal delivery or cesarean section with moderate anaemia (Hb 7-11 gm/dl) admitted in labor room and wards for anemia correction and agreeing to give written and informed consent will be included in the study.

A detailed history, general, physical and systemic examination will be performed in all subjects. Postpartum women coming for anemia correction will undergo screening tests on basis of peripheral blood smear examination and Red Blood Cell (RBC) indices.

Then subjects will be randomized in to two groups in 1:1, 108 subjects in each group

1. Group 1: One gram of intravenous iron isomaltoside was administered in a single dosage.
2. Group 2: 200 mg, 200 mg, and 200 mg of iron sucrose were given intravenously for three day totaling 600 mg.

Then the CBC will be done on the recruitment day followed by 21st day after therapy.

Figure 1: Iron isomaltoside transfusion in ward

Figure 2: Iron sucrose transfusion in ward

4. Results

To treat post-partum anemia after delivery, 216 women were randomly assigned to one of two groups: 108 subjects received iron isomaltoside, 108 subjects received iron sucrose.

There was no loss of follow-up for any of the participants after delivery. The results are as follows.

Table 2: Comparison of presence of pallor in both the groups

Pallor	Group 1 Percentage	Group 2 Percentage	Chi square test
+++	6.407	8.407	X2 = 3.4044
++	90.81	86.96	P = 0.631
+	2.77	4.629	Insignificant

As depicted here, majority of the subjects having pallor++, 6.407% in group 1 and 8.07% in group 2 having pallor +++, and few subjects had pallor +. P value 0.631, it is statistically insignificant.

Table 3: Comparison of peripheral smear report in study population

HPR	Group 1 Percentage	Group 2 Percentage	Chi Square Test
Microcytic hypochromic erythrocytesanemia	97.01	89.66	X2 = 3.4044
Normocytic with few microcytic erythrocytes	1.007	6.107	P = 0.631
Dimorphic erythrocytes	2.07	4.329	Insignificant

As depicted here, on peripheral smear report microcytic hypochromic erythrocytes seen in 97.01% of Group 1 subjects and 89.66% of Group 2 subjects, and dimorphic erythrocytes seen 2.07% of group 1 and 4.329% of group 2 subjects and normocytic with few microcytic erythrocytes seen in 1.007% of group 1 and 6.107% of group 2. It is statistically insignificant.

Table 4: Comparison of hemoglobin percentage before and after intervension in both the groups

Mean HB	Before intervention	After intervention	Std. Deviation
Iron Isomaltoside	9.1865	12.8328	.93867
Iron Sucrose	9.2191	11.4050	.96214
P value		<.001	
	Statistically Significant		

As depicted here, increase in mean hemoglobin value in iron isomaltoside group 1.4Gm% higher than iron sucrose group. With a P value of 0.001, this was statistically significant.

Table 5: Comparison of serum ferritin levels before and after intervension in both the groups

Serum ferritin Mean value	Before intervention	After intervention	Std. Deviation
Iron isomaltoside	54.1835	388.4719	17.82323
Iron sucrose	55.2034	241.1336	17.43720
P value	<0.005		
	Statistically significant.		

Among both the Groups, significant rise in serum ferritin seen in iron isomaltoside group than iron sucrose group, i.e 388.47 in iron isomaltiside group, 241.133 in iron sucrose group. With P value 0.005, this was statistically significant.

Table 6: Comparison of haematological parameter before and after intervension in both the groups

	Before intervention	After intervention
Iron Isomaltoside		
MCV	76.68±5.86	82.5±5.62
RBC Count (millions/cumm)	3.24±.271	3.78±.263
Iron Sucrose		
MCV	75.97±6.34	80.08±6.05
RBC Count (millions/cumm)	3.18±.28	3.77±.271
P Value	0.114	<0.004

In comparison to group 2, all haematological indicators showed a considerable improvement in group 1 during the post-treatment examination. For serum ferritin, packed cell volume, mean corpuscular volume, and hemoglobin level, the difference was extremely significant (p value <.001). With the exception of the RBC count, the change from baseline was highly significant in group 1 (p value <.001). The mean utilization in hemoglobin was found to be 2.086 gm/dl for iron isomaltoside and 1.776 gm/dl for iron sucrose, both of which were statistically significant (p value <.001). Notably, group 1's serum ferritin, a marker of iron reserves, increased much more than group 2's (p value <.001).

Table 7: Comparison of adverse reactions to drug after intervension in both the groups

	Iron Isomaltoside Group	Iron Sucrose Group	Chi Square Test
No reactions	104	103	X2 = 3.4044
Mild	3	4	P = 0.631
Moderate to severe	1	1	Insignificant

Among both the groups no reactions seen in most of the cases. Mild reactions seen in 3 cases of iron isomaltoside group, and 4 cases of iron sucrose group. Moderate to severe reactions are seen in one patient in each group. It is statistically insignificant.

Table 8: Comparison of total cost-effectiveness of both the treatments

	Iron Isomaltoside Group	Iron Sucrose Group
Drug	2,610	642.88 X 3= 1928.64
Normal saline	37.77	15.40 X 3=46.2
Drip set	134	134 X 3=402
5cc syringe	8	8 X 3=24
Total price	2,789.77	2,400.84

Among both the groups total price of treatment almost same, rupees 388.93 higher in isomaltoside group, since iron isomaltoside has additional advantage of single dose, early recovery from signs and treatment and early discharge.

4.1. Method of statistical analysis

In this study the following methods were used to analyse statistical results of the patients in both the groups.

For continuous data, number as well as percentage the results were averaged (mean ± standard deviation) as in cases of variables such as dichotomous data. These are presented in tables.

1. Chi–Squaretest used for comparison of proportion.
2. Student ‘T’ test

5. Discussion

The most prevalent type of nutritional anemia during pregnancy and the postpartum phase is iron deficiency anemia, which is a public health concern particularly in underdeveloped nations. There is a strong correlation between anemia throughout pregnancy and the postpartum phase and the morbidity of both the mother and the fetus.

According to our research, iron isomaltoside is a more successful treatment for postpartum anemia than iron sucrose, and it has the added benefit of only requiring a single dose and having a lower rate of side effects and less cost compared to iron sucrose.

Most of the cases in our study were illiterate people under 30years old, from low socioeconomic backgrounds, and they ate diets low in calories and proteins.

In developing countries like India, early marriage and childbearing are more prevalent since rural regions are less conscious of female education than metropolitan ones. Because of factors including illiteracy, cultural norms and beliefs, women's role in society, the priority put on male offspring, inadequate nutrition, poor personal cleanliness, and other factors, low socioeconomic status is associated with poor maternal health.[10]

In all, 216 postpartum women received 108 injections of iron isomaltoside and 324 injections of iron sucrose throughout our trial. Folic acid pills and deworming medication were administered to both groups, along with baseline examinations that included serum ferritin. A follow-up was conducted on the 21st day, during which time Hb, serum ferritin, and the baseline investigation were repeated.[11]

Veronika et al. observed that iron isomaltoside was similarly more effective than oral iron. After administering parenteral and oral iron for 1, 2, 4, and 6 weeks of treatment, the Hb levels were compared.[14] Additionally, they discovered that after 2, 4, and 6 weeks, the parenteral group's percentage of individuals reaching Hb>12 gm/dl was much higher than

that of the oral group. (p <.0001). Additionally, at 6 weeks, 91.4% of the participants in the parenteral group and 64.6% of the oral group saw an increase in hemoglobin levels of greater than 3 g/dl (p < 0.0001). The median time to attain Hb>12 gm/dl (14 versus 27 days, p =.0002) showed that the iron isomaltoside group responded more quickly than the oral iron group. Importantly, individuals with the most severe anemia showed a higher difference in the effectiveness of iron isomaltoside compared to oral iron.

Serum ferritin, a measure of the body's iron status, increased considerably in the iron isomaltoside group compared to the iron sucrose group in our research (67.6% versus 47.88%; p value <.001). Iron isomaltose's replenishment of iron reserves will stop IDA from happening again.

During our research, there were no notable negative impacts for any group. The incidence of adverse effects was lower in the iron isomaltoside group overall than in the iron sucrose group. In our study, the most common side effect in the iron sucrose group was nausea (9%), which was followed by burning at the infusion site, constipation, dizziness (6%) and cramping in the muscles (7%). But there wasn't a discernible difference between the groups.[12]

Headache (8%) was the most frequent adverse effect in the iron isomaltoside group, followed by nausea, dizziness, and hypertension (5%). In neither group was there a higher frequency of hypersensitive reactivity. Four individuals in the iron sucrose group and three in the isomaltoside group experienced mild hypersensitivity responses.[13]

According to Veronika et al., there were no major side effects in either group and a decreased incidence of adverse effects in the parenteral group compared to the oral group. Constipation was the most frequent side effect in the oral group and urticarial in the parenteral group.[14]

Parentral iron was linked to a greater frequency of skin issues, such as purities and rashes, according to Linus LT LEE and Wendy et al. However, these issues were extremely small and momentary, and they went away in five to fifteen minutes. After receiving the second dosage of iron isomaltoside, 37.5% of these individuals had moderate, temporary rashes and repeated purities. No phlebitis event in the parental group.[15]

6. Conclusion

The result of this study indicate that iron isomaltoside causes significantly higher rise in Hb level as compared to iron sucrose. Notably, serum ferritin which a marker of iron stores increased significantly in iron isomaltoside group versus iron sucrose group which prevents recurrence of iron deficiency anemia.

Side effects were minor and comparable both groups. Iron isomaltoside has an additional advantage of single dose administration as compared to multiple doses required in iron sucrose administration.

NOTE: Iron Isonaltosde is not widely used in India, due to drug not easily available in India, and it is newer drug.

7. Source of Funding

None.

8. Conflict of Interest

None.

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Cite this article: Bhosle PB, Bidri SR, Yaliwal RG. A comparative study of iron isomaltoside versus iron sucrose in treating anemia in postpartum. *Indian J Obstet Gynecol Res*. 2025;12(2):272–277.