



## **Comparative study on intravenous iron sucrose versus intravenous ferric carboxymaltose in the management of iron deficiency anaemia in pregnancy**

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### **Abstract**

**Background:** To evaluate the efficacy and safety of intravenous Ferric Carboxymaltose (FCM) in comparison with intravenous Iron sucrose complex (ISC) for treatment of iron deficiency anaemia in pregnancy.

**Methods:** Two hundred subjects had been randomized to get administered with either intravenous FCM or ISC. Primary outcome had been elevation in haemoglobin from baseline to after 3 months. Results were analysed.

**Results:** Among the ISC group, 29 subjects had mild anaemia while 69 subjects had moderate anaemia. Among the FCM group, 27 subjects had mild anaemia while 72 subjects had moderate anaemia. Both the study groups showed improvement in the haemoglobin levels following treatment. However; at 3 months interval, significantly better results were obtained while comparing the haemoglobin levels in between the study groups.

**Conclusion:** Both FCM and ISC were effective for treating Anaemia among pregnant subjects. However; has the advantage of a large dose early rise in Hb level.

**Key words:** Iron, Sucrose, Carboxymaltose

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### **Introduction**

Anaemia is a major global health issue, with iron deficiency anaemia being the most common type of nutritional deficiency affecting both developed and developing countries. Iron deficiency anaemia is responsible for a significant number of maternal and perinatal deaths worldwide. The prevalence of anaemia is particularly high in South Asian countries, with India accounting for a large proportion of global maternal deaths due to anaemia. The reasons for high incidence of anaemia in India include low dietary intake of iron, poor bio-availability of iron, and chronic blood loss during menses, among others.<sup>1,2</sup>

Prophylactic oral iron is recommended during pregnancy to meet the increased demand for iron. However, compliance with oral iron therapy is often an issue due to gastrointestinal side effects.<sup>3</sup> Parenteral therapy is often needed for moderate to severe anaemia, particularly in the late second and third trimesters. Iron sucrose complex (ISC) is a commonly used parenteral iron preparation for anaemia in pregnancy.<sup>4</sup> Ferric Carboxymaltose (FCM) is a newer type of parenteral iron preparation that has been extensively studied for the treatment of postpartum anaemia and other diseases associated with anaemia.<sup>5</sup> However, there is limited literature on the use of FCM in pregnancy. This study was conducted to evaluate the efficacy, safety, and cost-effectiveness of FCM compared with ISC for the treatment of moderate to severe iron deficiency anaemia in pregnancy.

## **Methods**

This research recruited pregnant females who had been diagnosed with moderate to severe iron deficiency anaemia. Overall; two hundred subjects had been randomized to get administered with either intravenous FCM or ISC. Subjects having haemoglobin over 60 g/L as well as less than 100 g/L and iron deficiency anaemia had been chosen for the research. The study excluded those who had anaemia because of other reasons than iron deficiency; any chronic infections such as hepatitis as well as HIV; serum transaminases over one and a half times the upper limit of normal; serum creatinine level of over 2.0 mg/dL or history of allergic reaction to intravenous iron infusion. A thorough examination was conducted, which involved anthropometric measurements, general physical examination, and obstetric evaluation. Following the determination of the total iron deficit, patients in the FCM group were given intravenous FCM. The maximum dose administered per session was 1000 mg, which was mixed with two hundred millilitres of 0.9 percent normal saline and infused intravenously over a period of thirty minutes. In contrast, patients in the ISC group were given i.v. ISC at a dose of 300 mg in 200 ml of normal saline over fifteen to twenty minutes, twice a week until the dosage was completed, not exceeding 600 mg per week. Follow-up was done up to three months. All statistical analysis was carried out using SPSS version 17.0

## **RESULTS**

Among the ISC group, 29 subjects had mild anaemia while 69 subjects had moderate anaemia. Among the FCM group, 27 subjects had mild anaemia while 72 subjects had moderate anaemia. Both the study groups showed improvement in the haemoglobin levels following treatment. However; at 3 months interval, significantly better results were obtained while comparing the haemoglobin levels in between the study groups.

**Table 1: Distribution of anaemia**

<b>Degree of anaemia</b>	<b>ISC group</b>	<b>FCM group</b>	<b>p- value</b>
<b>Mild</b>	<b>29</b>	<b>27</b>	<b>0.6445</b>
<b>Moderate</b>	<b>69</b>	<b>72</b>	
<b>Severe</b>	<b>2</b>	<b>1</b>	
<b>Total</b>	<b>100</b>	<b>100</b>	

**Table 2: Comparison of haemoglobin levels before and after treatment**

Mean haemoglobin levels	ISC group	FCM group	p- value
Before treatment	7.95	7.38	0.121
4 weeks after treatment	9.51	9.31	0.228
3 months after treatment	10.98	9.56	0.000 (Significant)

**Table 3: Adverse events**

Adverse events	ISC group	FCM group
Pain/burning sensation at injection site	10	3
Swelling at injection site	5	4
Nausea/vomiting	3	0
Gastritis	2	4

## DISCUSSION

Iron deficiency is the most common nutritional deficiency worldwide; it affects 1.6 billion people (nearly a quarter of the world's population). Iron deficiency (ID) and iron deficiency anemia (IDA) are often encountered in the general population, particularly among children and women with abnormal uterine bleeding (AUB) and during pregnancy as well as postpartum period. Since iron is the functional component of hemoglobin and is also an essential constituent in a large number of enzymes important for all major metabolic pathways reduced iron levels limit energy production. Common symptoms that may result from ID are fatigue exhaustion susceptibility to stress and underperformance.<sup>7-10</sup> This study was conducted to evaluate the efficacy, safety, and cost-effectiveness of FCM compared with ISC for the treatment of moderate to severe iron deficiency anaemia in pregnancy.

Among the ISC group, 29 subjects had mild anaemia while 69 subjects had moderate anaemia. Among the FCM group, 27 subjects had mild anaemia while 72 subjects had moderate anaemia. Both the study groups showed improvement in the haemoglobin levels following treatment. However; at 3 months interval, significantly better results were obtained while comparing the haemoglobin levels in between the study groups. Jose A et al evaluated the efficacy and safety of intravenous Ferric Carboxymaltose. (FCM) in comparison with intravenous Iron sucrose complex (ISC) for treatment of iron deficiency anemia in pregnancy. One hundred patients were randomized to receive either intravenous FCM or ISC. Primary outcome was rise in hemoglobin (Hb) from baseline after 12 weeks. Secondary outcomes were change in RBC indices, serum iron studies, improvement in fatigue scores, number of visits and perinatal outcome. Mean rise in Hb at 12 weeks was significantly higher in FCM group (29 g/L vs 22 g/L; p value <0.01). FCM was associated with greater improvement in fatigue scores. Number of visits were significantly less in FCM group. No serious adverse events were noted in either group. Treatment with FCM resulted in rapid replenishment of iron stores in pregnant women with significantly higher Hb rise over a 12 week period.<sup>11</sup>

Shin, H. W et al assessed the comparative efficacy and safety of commonly used intravenous (IV) iron formulations, ferric carboxymaltose (FCM), and iron sucrose (IS) in the treatment of IDA in obstetric and gynecologic patients. They systematically searched PubMed, EMBASE, Cochrane CENTRAL, and Google Scholar for eligible randomized controlled trials (RCTs) comparing IV iron replacement using FCM and IS up to October 2019. The primary outcome was to compare the efficacy of FCM and IS, assessed by measuring serum hemoglobin (Hb) and ferritin levels before and after iron replacement. The secondary outcome was to compare the safety of FCM and IS, assessed by the incidence of adverse events during iron replacement. The meta-analysis was performed using RevMan 5.3. They identified 9 RCTs with 910 patients (FCM group, n=456; IS group, n=454). Before iron replacement, FCM and IS group patients had similar baseline Hb and ferritin levels. Following iron replacement, patients who received FCM had higher Hb and ferritin levels than patients who received IS. FCM group showed a lower incidence of adverse events following iron replacement than IS group. Serious adverse events were not reported in any group. FCM group showed better efficacy in increasing Hb and ferritin levels and a favorable safety profile with fewer adverse events compared with IS group for IDA treatment among obstetric and gynecologic patients.<sup>12</sup>

## **CONCLUSION**

Both FCM and ISC were effective for treating Anaemia among pregnant subjects. However; has the advantage of a large dose early rise in Hb level.

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