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# A prospective interventional study to observe the effectiveness of parenteral iron infusion of iron isomaltoside 1000 (Fur – IV) in obstetrics and gynecology patients suffering from moderate to severe iron deficiency anaemia

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ABSTRACT

**Background:** Anaemia during pregnancy is allied with maternal and foetal complications like increased risk of intrauterine growth retardation, prematurity, low birth weight, and maternal and infant mortality. The agent iron isomaltose 1000 (Fur-IV) combines iron and isomaltose 1000 for slow, controlled release to reduce the risk of free iron toxicity and provide flexibility and convenience for high dose administration. Iron isomaltoside has been shown to be effective in the treatment of IDA in many treatment groups compared to intravenous iron sucrose and FCM.

**Materials and Methods**: It is a prospective interventional study which is conducted to observe an increase in hemoglobin levels in obstetric and gynecological department patients suffering from IDA in whom oral iron preparation was ineffective or in case of clinical need to supply iron rapidly via single infusion of iron isomaltoside 1000. Each patient in the study received 500 mg single intravenous infusion. After this, patient was followed up and haemogram was repeated after 15 and 30 days of infusion while investigation for serum ferritin and serum iron was repeated after 30 days.

**Results:** Average Hb concentration in increased by 30.86% to 9.88 g/dL after 30 days of infusion. There is statistically significant difference between baseline values and post infusion 30 days values for serum ferritin and serum iron (p-value <0.0001 for both).

**Conclusion:** IV iron isomaltoside administration was well tolerated in patients with gynecological IDA who were intolerant or unresponsive to oral iron therapy or who required rapid iron administration.



## 1. Introduction

Iron deficiency anaemia (IDA) is a one of the universal health issues.[1,2] Anaemia during pregnancy is one of the important factors associated with several maternal and foetal complications. It is associated with an increased risk of intrauterine growth retardation, prematurity, low birth weight (LBW), and maternal and infant death. So, it's important to correct iron deficiency anaemia as early as possible. Intravenous (IV) iron therapy provides a quick and effective means of correcting iron levels and in many cases, it is superior to oral iron therapy.[3] Although treatment with oral iron may be appropriate for some patients, intolerance, non-standard absorption due to inflammation, noncompliance with treatment, and severe iron deficiency may not adequately treat anaemia with oral iron.[3] International guidelines suggest IV iron as the preferred option for correcting IDA in numerous conditions

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and when iron requirements are high. This is because it is more effective, better tolerated, and improves quality of life (QoL) than oral iron supplements.[3–5]

Oral iron is the recommended first-line treatment during pregnancy for mild IDA and non-anaemia iron deficiency cases. Various oral iron formulations are iron(II) salts, iron(III) polymaltose complexes, and liposomal iron.[6,7] Existing ferrous iron salts are ferrous sulfate, ferrous gluconate and ferrous fumarate. None seem to be better than the others and have similar rates of side effects.[8] One of the few iron(III) compounds available orally is the iron(III) polymaltose complex (IPC) dextriferon. There are few studies related to the use of iron polymaltose (IP) during pregnancy, but to date there are no serious adverse events (SAEs) have been reported up to now.[9] Liposomal iron (a ground work of ferric pyrophosphate), new generational oral iron preparation has minimal data available about its use in pregnancy.

Parenteral iron therapy is currently widely used in the treatment of IDA in a diverse group of diseases. Iron agents for intravenous administration are currently commercially available: iron sucrose, iron carboximaltose, iron isomaltose 1000 (Fur-IV). Intravenous iron-sucrose complexes have a side-effect profile better than oral iron preparations and are safe and effective during pregnancy.[10] Therefore, they are widely used in hospitals as intravenous iron preparations. The maximum dose in a single dose should not exceed 200 mg. The infusion time should be at least 15 minutes for 100 mg and at least 30 minutes for 200 mg.[11] Iron isomaltoside 1000 (popular as ferric derisomaltose) and iron carboxymaltose are intravenous iron preparations developed for the rapid correction of IDA, especially in patients who are unable to respond or tolerate the oral iron.[12,13] Both iron isomaltoside and iron carboxymaltose effectively correct IDA, but have different safety profiles.[14–17] Several studies have reported that ferric (iron) carboxymaltose causes high rates of hypophosphatemia by acutely increasing circulating concentrations of complete and biologically active fibroblast growth factor 23, which causes hypophosphatemia by stimulating urinary phosphate excretion and decreasing serum 1,25-dihydroxyvitamin D levels.[18–20] Severe hypophosphatemia can lead to serious complications such as rhabdomyolysis, heart failure, and respiratory failure and chronic hypophosphataemia can lead to complications due to osteomalacia and fractures.[21,22] Previous clinical trials may suggest a lower risk of hypophosphataemia with iron isomaltoside than with ferric carboxymaltose,[14,16,17,23,24] Data from randomized trials directly comparing the two formulations are limited.

Iron isomaltoside 1000 (Fur – IV) is a combination of iron and isomaltoside 1000 (a carbohydrate) that are strongly bound, allowing for slow and controlled release, thereby reducing the risk of free iron toxicity, and offering high dose and administration flexibility and convenience. Iron isomaltoside is a third-generation parenteral iron available as 100 mg/mL, which can be administered up to 20 mg/kg body weight, given by slow IV injection over 30 minutes. If the requirement exceeds 20 mg/kg of body weight, the dose must be divided into two administrations with an interval of at least 1 week. Iron isomaltoside has been shown to be effective in the treatment of IDA across multiple therapeutic groups and compared to IV iron sucrose and FCM. It has low immunogenic potential, low labile iron release potential and does not appear to be associated with clinically significant hypophosphataemia. It is an well-tolerated effective treatment of anaemia across diverse therapeutic ranges with a positive safety profile. Therefore, this study is conducted to observe the rise in hemoglobin (Hb) level in obstetrics and gynecology patients suffering from IDA through a single infusion of iron isomaltoside 1000 (Fur – IV).

## 2. Materials and Methods

It is an interventional prospective study including females >18 years age attending Obstetric and gynaecological outpatient patient department (OPD) or IDA indoor patient with intolerant oral iron preparation or having a clinical need of quick iron delivery. Patients were counselled for follow-up and written informed consent was taken. Patients excluded from the study those were suffering with acute anaemia Hb <7 mg/ dL, or allergic to intravenous iron compounds or having thalassemia. Institutional Ethics Committee granted the approval to conduct the study. All the female patients attending Obstetrics and Gynaecology OPD or indoor patients who were diagnosed cases of IDA and fell under the inclusion criteria of the study were enrolled and followed up. Data were collected for 60 patients over a period of 3 months and arrived in CRFs (Case Record Forms). A thorough medical history of the participants was taken and iron demand of the patient was calculated by the Ganzoni formula (2.4*Hb deficit in g% (12 – patient's Hb) × body weight) before IV iron isomaltoside 1000 administration by the Obstetrics and Gynaecology department. Baseline investigation of patients including haemogram, serum ferritin and serum iron were done and data were recorded for the same. Each mL of Fur I.V. contains 100 mg of elemental iron. Each vial of Fur I.V. is single-dose only. It is diluted in 100 mL - 500 mL injection of 0.9% Sodium Chloride. Last diluted concentration should be greater than 1 mg iron/mL given IV over 40 minutes after checking the allergic reactions. Each patient in the study obtained a single intravenous infusion of 500 mg i.e. 5 ml of isomaltoside 1000 (Fur–IV). After a single IV infusion of iron isomaltoside 1000 (Fur–IV), the patient was followed up and haemogram was repeated after 15 and 30 days of infusion while investigation for serum ferritin and serum iron was repeated after 30 days. To analysis statistically, data were arrived in an excel sheet.

## 3. Results

Table 1 shows that baseline average Hb concentration among study participants was 7.55 g/dL, which increased by 16.15% to 8.77 g/dL after 15 days of infusion. Average Hb concentration in increased by 30.86% to 9.88 g/dL after 30 days of infusion.

**Table 1:** Average haemoglobin concentration on follow-up

| Follow-up | Haemoglobin concentration (g/dL) | Difference of Haemoglobin concentration from baseline (g/dL) |
|---|---|---|
| Baseline | 7.55 | 0 |
| After 15 days of infusion | 8.77 | 1.22 |
| After 30 days of infusion | 9.88 | 2.33 |

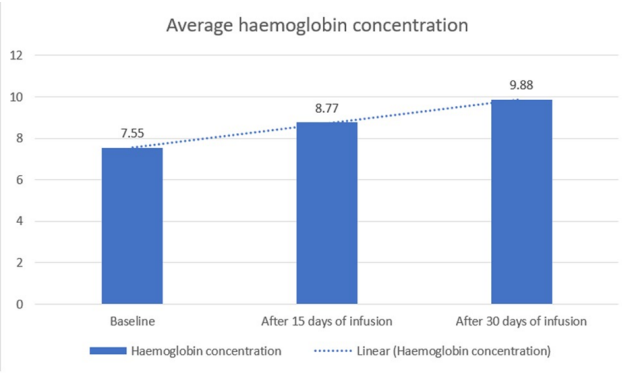


**Fig. 1:** Trend of rise in average haemoglobin concentration after intravenous infusion of iron isomaltoside among study participants

**Table 2:** Average laboratory indicators on follow-up

| Follow-up | Laboratory indicators for iron deficiency anaemia(Mean + SD) | | *p-value |
|---|---|---|---|
| | Baseline | After 30 days of infusion | |
| Serum ferritin (ng/mL) | 27.85 ± 12.87 | 91.94 ± 14.75 | < 0.0001 |
| Serum Iron ($\mu$g/dL) | 25.91 ± 6.64 | 95.17 ± 9.36 | < 0.0001 |

*Student t-test
p-value < 0.05 significant

Table 2 shows average increase in laboratory indicators for IDA, i.e. serum ferritin and serum iron. After 30 days of infusion, average serum ferritin levels increased by 3.3 times while average serum iron levels increased by 3.7 times, while only 2 (3.33%) patients had a minor adverse event, which was uneventful. There is statistically significant difference between baseline values and post infusion 30 days values for serum ferritin and serum iron (p-value <0.0001 for both).

**Table 3:** Adverseevent summary

| S. No | Adverse Event | Number of Subjects N (%) | Serious/ Non-Serious |
|---|---|---|---|
| 1 | Itching | 1 (1.67%) | Non- Serious |
| 2 | Headache | 1 (1.67%) | Non- Serious |

## 4. Discussion

This study was conducted to evaluate the increase in concentration of hemoglobin level during parenteral iron infusion of iron isomaltoside 1000 (Fur–IV) in gynaecological patients with IDA. Iron isomaltoside is accepted in more than 30 countries worldwide for treatment of iron deficiency while oral iron preparations are ineffective or unavailable or when rapid iron delivery is clinically indicated. Oral iron supplements can also root few side effects like upset stomach, constipation or dark-stools. Iron levels do not increase effectively if the person cannot take oral iron supplements. Moreover, other injectable iron preparations like iron sucrose, iron dextran, etc may cause side effects such as headache, flushing, joint & muscle pain, dizziness, nausea, rash, pain and inflammation over the injection site, fever or chills. Intravenous (IV) iron, especially in single doses, may improve compliance, reduce doctor visits, and improve overall quality of life.

An advantage of this study is that it included a gynaecological population with IDA of various aetiologies. IDA was confirmed in all patients at the beginning of the study by measuring haemogram, serum iron, and serum ferritin. A mean Hb increase of 2 g/dL from baseline was found at the end of week 4 for iron isomaltoside. Furthermore, it was also observed that the time required for hemoglobin to increase by 2 g/dL was shorter with iron isomaltoside. This was most likely due to the fact that iron isomaltoside was administered in higher doses for a shorter period of time. Faster and/or greater improvements were found with iron isomaltose for all biochemical efficacy parameters measured (Hb, s-ferritin and s-iron). These results are consistent with previous studies reporting the effect of iron isomaltoside on significantly increasing iron-related parameters.[25–34]

Treatment with iron isomaltoside was tolerated well. Compared to iron isomaltoside, the iron is more weakly bound to iron sucrose.[35] This is related to catalytic/labile iron, which is supposed to cause increased oxidative stress with potential significances on long-term iron sucrose toxicity.[36,37]

Several clinical trials of iron isomaltoside have been reported, mostly of short duration, and have been shown to improve markers of IDA in dialysis patients;[25,32] with

chronic kidney disease who are well tolerated[33] patients with chronic heart failure [CHF];[26] inflammatory bowel disease[29,30,38] and underlying cancer[39] patients who have undergone heart surgery[28] and women with postpartum haemorrhage.[31]

Therefore, treatment of IDA with iron isomaltoside corrects the haematological parameters iron isomaltoside reduces symptoms such as fatigue and improves quality of life because the treatment period is shorter to achieve clinically necessary iron levels. In a sub-analysis of women suffering with acute fatigue after postpartum haemorrhage, a single dose of iron isomaltoside resulted in statistically significant and clinically appropriate reduction in cumulative physical fatigue up to 12 weeks postpartum, compared to current oral iron treatment methods.[40]

Administering the full iron replacement dose in one visit will provide optimal convenience and improve overall pharmacoeconomics for both patient (less disruption to life, less time away from home/work, decreased injection numbers and less exposure to the potential side effects) and hospital/medical services (reduced the quantity of visits, decreased physician and nurse time and enhanced outpatient management and cost efficiencies).[41,42] The National Institute for Health and Care Excellence guidelines of year 2015, which recommend that high-dose, low frequency intravenous iron be considered as the treatment of choice for adults and young population with IDA not undergoing haemodialysis, supported this.[43] Besides this, the guidelines rank iron isomaltoside as the utmost profitable/cost-effective intravenous iron for non-dialysis inpatients.[43] In one of the latest trials, infusions of iron isomaltoside was given as single doses up to 1500 mg and as cumulative doses up to 3000 mg over a short periods of time were completed without any concern of safety, representing a promising therapeutic alternative in current practice.[38]

## 5. Conclusion

This resulted to a conclusion that intravenous iron isomaltoside has been well tolerated in gynaecological patients with IDA who are intolerant or unresponsive to oral iron therapy or in case of rapid iron administration is needed. There was no evidence of serious hypersensitivity reactions, including hypophosphataemia. Intravenous administration of iron isomaltoside single dose produced a faster and transiently greater haemoglobin response in the first 2 weeks and was effective in confirming an enhancement in haemoglobin concentration in 4 weeks. The current study contributes to the body of evidence representing that iron isomaltoside is efficacious in the single visit treatment of IDA.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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