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Effectiveness, Adherence and Tolerability to Iron (III) Hydroxide Polymaltose in Pregnant Women with Iron Deficiency Anemia: Findings from a Multicenter, Prospective, Single-Arm Study in Angola

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Abstract

Introduction: Iron deficiency anemia (IDA) is the most common hematologic complication during pregnancy, particularly in low- and middle-income countries. This study aimed to evaluate the efficacy and adherence to Iron (III) Hydroxide Polymaltose in improving hemoglobin (Hb) levels in pregnant women with IDA in Angola. **Methods:** A prospective, interventional, multicenter study was conducted in 3 healthcare centres in Angola. Iron (III) Hydroxide Polymaltose syrup (Hemoforce Gravida®) was used. A total of 200 pregnant women were recruited; however, 11 were lost to follow-up. Hence, a total of 189 pregnant women with Hb < 10.5 g/dL were treated with the syrup for 28 days. Participants received Hemoforce Gravida (5 ml once or twice daily, or 10 ml once daily) for 28 days. The primary objective was to measure haemoglobin levels before and after treatment. Secondary objectives were to evaluate adherence, tolerability, and clinical symptoms. **Results:** After 28 days, a mean hemoglobin increase of 1.45 ± 0.92 g/dL was observed ($p < 0.001$), demonstrating significant efficacy. Clinical improvement, particularly reduced fatigue, was reported by 180 participants (95%). Treatment adherence was 67.7% participants demonstrated high adherence, while 32.3% showed moderate adherence. Gastrointestinal intolerance, the main reason for switching previous supplements, was less frequent with Iron (III) Hydroxide Polymaltose. Physicians who participated in the study have provided a favorable opinion on quality-of-life outcomes for enrolled patients following treatment. Also, self-patient-reported outcomes following treatment suggested an improvement in quality of life. **Conclusion:**

Iron (III) Hydroxide Polymaltose syrup is effective and well-tolerated in treating IDA during pregnancy and represents a viable option in resource-limited settings.

Keywords

Iron Deficiency Anemia, Pregnancy, Ferric Hydroxide Polymaltose Complex, Hemoglobin, Angola

1. Introduction

During pregnancy, red blood cell mass increases by approximately 35%, while plasma volume expands by 40% - 50%, resulting in physiological haemodilution and consequent reductions in haemoglobin and haematocrit levels [1]. Iron requirements rise progressively during the second and third trimesters due to increased demands from foetal, placental, and maternal tissue development [2]. As a result, iron deficiency becomes the leading cause of anaemia in pregnancy [3].

Iron plays a fundamental role in several physiological processes, including oxygen transport, mitochondrial energy production, DNA synthesis, and free radical elimination [4]. Anaemia is defined as haemoglobin levels below normal thresholds for a given gestational stage, with the World Health Organization (WHO) defining anaemia in pregnancy as haemoglobin (Hb) < 11.0 g/dL, adjusted for altitude and smoking status [5].

Globally, anaemia affects approximately 27% of the population, corresponding to nearly 1.93 billion individuals. Sub-Saharan Africa bears a disproportionately high burden, with an estimated 190 million cases. Women of reproductive age are particularly affected, including approximately 38% of pregnant women [6].

A systematic review and meta-analysis entitled "Prevalence and determinants of anemia among pregnant women in sub-Saharan Africa", which analyzed twenty-five studies covering 15,061 pregnant women, reported an overall prevalence of anemia in pregnancy in sub-Saharan Africa of 35.6% pregnant women. It was also reported that women who did not receive iron and folic acid supplementation were 1.82 times more likely to develop anemia compared to those who did. In addition, women in the third trimester of pregnancy were 2.37 times more likely to develop anemia than those in the first and second trimesters [7].

The World Health Organization estimates that 22.7% of pregnant women in industrialized countries are anemic, while in developing countries this figure is around 52% [8].

Iron deficiency remains the most common cause of gestational anaemia, primarily due to inadequate dietary intake and increased physiological demand during pregnancy [4] [9]. Untreated anaemia is associated with significant maternal and foetal complications, including preterm birth, foetal growth restriction, placental insufficiency, maternal infections, cardiovascular strain, prolonged hospitalization, and postpartum depression [3] [4].

Despite the substantial burden, there is limited published evidence on gestational anaemia in Angola, highlighting the need for further research in this setting [8].

2. Scientific Objective

To evaluate the efficacy, adherence, and tolerability of Iron (III) Hydroxide Polymaltose syrup (Hemoforce Gravida®) in pregnant women with anaemia, measuring haemoglobin response, symptom improvement, adherence, and adverse effects.

3. Methodology

3.1. Study Design and Setting

A multicenter, prospective, interventional cross-sectional study of Iron (III) Hydroxide Polymaltose syrup (Hemoforce Gravida®, Shalina Healthcare) in pregnant women diagnosed with Iron deficiency anemia conducted from December 2023 to May 2024 in Luanda, Angola. To confirm the iron deficiency anemia among pregnant women, hemoglobin level was checked using a small blood drop from a finger prick, applying it to a test strip in a Hemoglobinometer (A digital device for measuring hemoglobin). As iron deficiency anemia is very common in pregnant women, serum ferritin level and PCV were not performed for eligibility. Based on the hemoglobin level below 10.5 g/dl, a total of 200 pregnant women were recruited; however, 11 were lost to follow-up. Hence, a total of 189 pregnant women were considered for the final study analysis from 3 centres listed below:

- Lucrécia Paim Maternal Hospital (129 participants)
- Mãe Jacinta Health Center (52 participants)
- N'Gangula Hospital (8 participants)

3.2. Population/Sample

200 pregnant women aged 18 - 48 with newly diagnosed IDA were enrolled; 11 were lost to follow-up, leaving 189 for final analysis.

3.3. Study Product

Hemoforce Gravida syrup contains Iron (III) Hydroxide Polymaltose (60 mg elemental iron per 5 ml), folic acid, vitamin B12, vitamin C, copper, zinc, and manganese. Dosage followed physician discretion for 28 days, self-administered at home.

3.4. Inclusion Criteria

Pregnant women aged 18 - 48 with Hb < 10.5 g/dL and voluntary consent.

3.5. Data Collection

A paper data collection form was used for each participant to capture the information on demographics, clinical symptoms, haemoglobin levels, safety, adher-

ence, tolerability and quality-of-life assessments were recorded at baseline and at Day 28 as per the requirements.

3.6. Statistical Analysis

Initial data was captured using Excel 2021. However, the statistical analysis was performed using SPSS version 20.0, comparing baseline and post-treatment Hb levels. Statistical significance was set at $p < 0.05$. Other parameters were also analysed based on the secondary objective of this study. The same is detailed in the results section.

3.7. Ethical Considerations

Approved by Angola's National Executive Council of the Medical Association. Written informed consent was obtained.

4. Results

Of the 200 pregnant women aged 18 to 48 years with a new diagnosis of iron deficiency anemia, 11 did not return for follow-up. A total of 189 participants completed the study.

The mean age of the participants was 28.28 ± 6.56 years (ranging from 18 to 43 years), the mean weight was 67.72 ± 15.39 kg (ranging from 37 to 120 kg), and the mean height was 149.27 ± 16.10 cm (minimum 120 cm and maximum 177 cm), as shown in Table 1, which presents the demographic characteristics of the participants (Table 1).

Table 1. Demographic characteristics of the participants (n = 200).

Variable	Mean	Standard Deviation	Minimum	Maximum
Age (years)	28.28	6.56	18	43
Weight (kg)	67.72	15.39	37	120
Height (cm)	149.27	16.10	120	177

As shown in Figure 1, the distribution of the study participants by age group. It is observed that 28.4% of the patients were in the 25 - 29-year age group, considered the peak fertility period in developed countries, and the main age group associated with the occurrence of anaemia during pregnancy.

As shown in Figure 2, the distribution of study participants according to the stage of pregnancy shows both absolute and relative frequencies. Most participants were in the second trimester, 102 (54.0%), followed by the third trimester, 63 (33.3%), while the remaining 24 (12.7%) were in the first trimester.

As shown in Figure 3, headache (33.0%) was the most common symptom, followed by light-headedness (27.9%) and fatigue/weakness (23.5%). Other symptoms included shortness of breath (7.8%), irritability (5.6%), and fast heart rate (2.2%). Overall, non-specific symptoms such as headache, dizziness, and fatigue predominated.

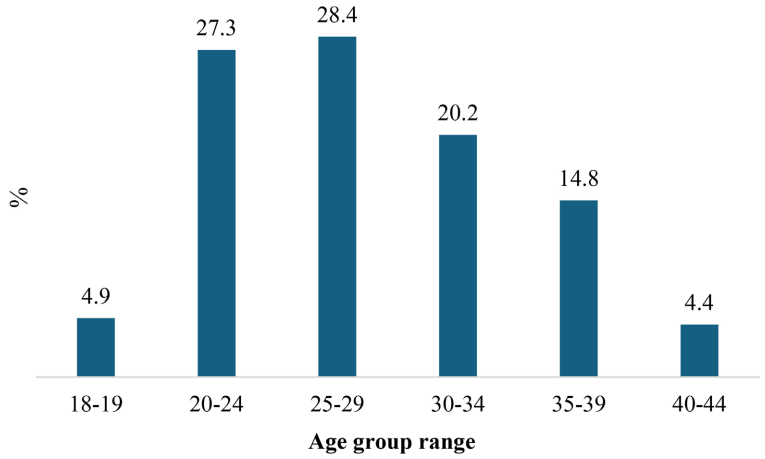

Figure 1. Bar chart presenting the distribution of study participants according to age groups.

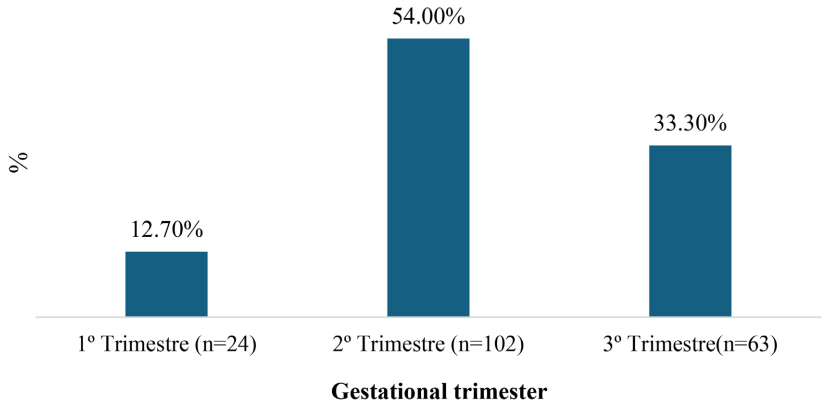

Figure 2. Bar chart presenting the distribution of study participants according to gestational trimester.

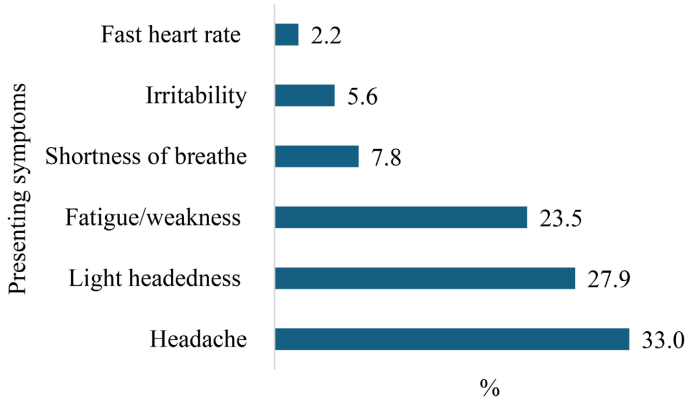

Figure 3. Bar chart presenting the distribution of study subjects according to symptoms presented during the screening consultation.

As shown in **Figure 4**, the distribution of study participants in relation to fatigue at the baseline visit. Of the 42 participants who presented with fatigue, 25 (59.52%) reported mild fatigue and 17 (40.48%) reported moderate fatigue.

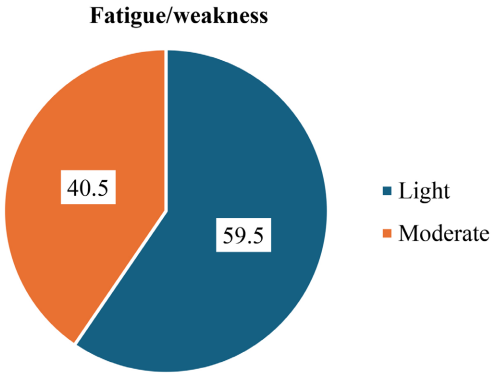

Figure 4. Pie chart presenting the distribution of study subjects according to baseline fatigue category.

As shown in Figure 5, the distribution of Hemoforce Gravida syrup dosing among the study subjects showed that 109 (57.7%) women were advised to take 5 ml of syrup twice daily, while 64 (33.9%) were advised to take 5 ml once daily. Additionally, 16 (8.5%) women were advised to take 10 ml of syrup once daily. The dosage regime was decided as per the investigator's discretion, depending upon the hemoglobin level at the entry stage of the study participation, as per the trimester status of the pregnant women. Hence, variation can be seen among participants.

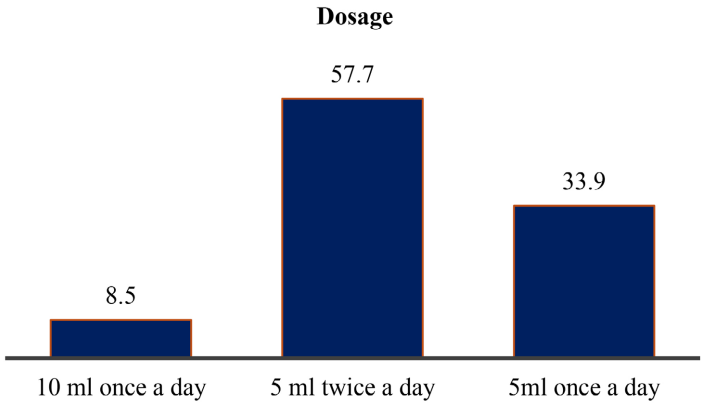

Figure 5. Bar chart presenting the distribution of dosage of hemoforce syrup at baseline.

Regarding the use of other supplements, 49.7% reported also using ferrous sulfate.

The reasons for changing supplements were varied: most participants, 31 (33.0%), reported poor gastric tolerance, followed by 25 (26.6%) who cited a metallic taste as the reason. Constipation was reported by 16%, while 10.6% mentioned low efficacy of the previously used product.

Concerning adherence to Hemoforce Gravida syrup, a self-reporting tool to assess medication-taking behaviour was used. These were defined as "high", "moderate", "poor" and "no" categories. This assessment was done at the end of the study during the final visit, 128 (67.7%) participants demonstrated high adher-

ence, while 61 (32.3%) showed moderate adherence. There were no participants reported in the "Poor" and "No" categories.

Regarding improvement in fatigue levels after using the syrup, 22 (52.38%) women experienced a significant improvement, 18 (42.85%) a moderate improvement, and only a small proportion, 2 (4.76%), reported a slight improvement.

As shown in Figure 6, the change in hemoglobin level (g/dL) in study participants after administration of Hemoforce syrup. A mean improvement of 1.45 ± 0.92 g/dL in hemoglobin level was recorded. After applying the paired t-test, a significant improvement was observed ($p < 0.001$). Within a short period of 28 days, hemoglobin levels increased by 14.99%.

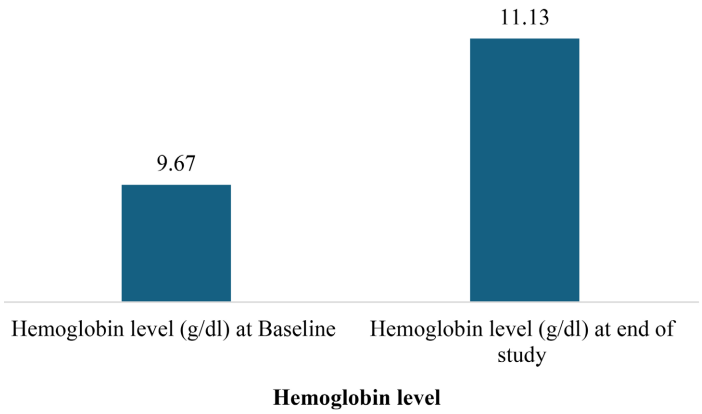

Figure 6. Bar chart presenting comparison of the mean Hb level between baseline and final values.

As shown in Figure 7, the majority of participants were rated as having satisfactory quality of life (63.0%), followed by good (33.3%). A small proportion reported very good (3.2%) and moderately improved (0.5%) outcomes. Overall, most physicians demonstrated favorable quality-of-life outcomes following treatment.

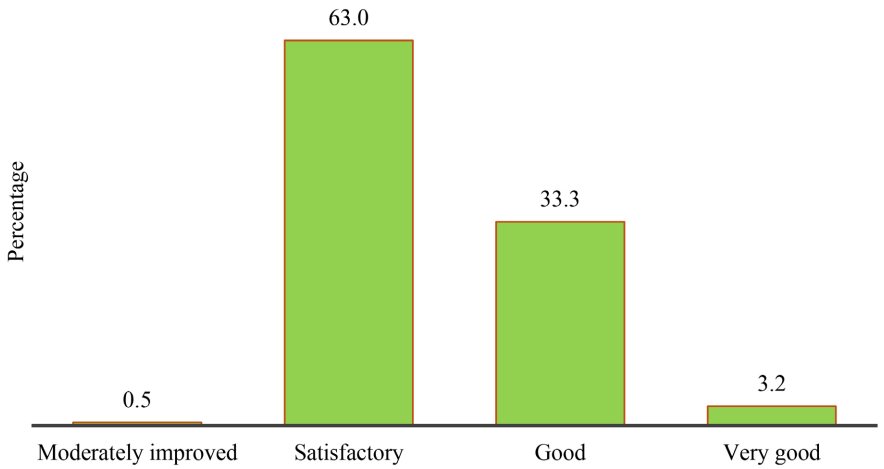

Figure 7. Bar chart presenting the distribution of study subjects according to the Physician's Global assessment of quality of life.

As shown in Figure 8, the majority of participants reported good (48.1%) and satisfactory (48.1%) quality of life, while a small proportion reported very good (3.7%) outcomes. Overall, patient-reported outcomes indicate favorable improvement in quality of life following treatment.

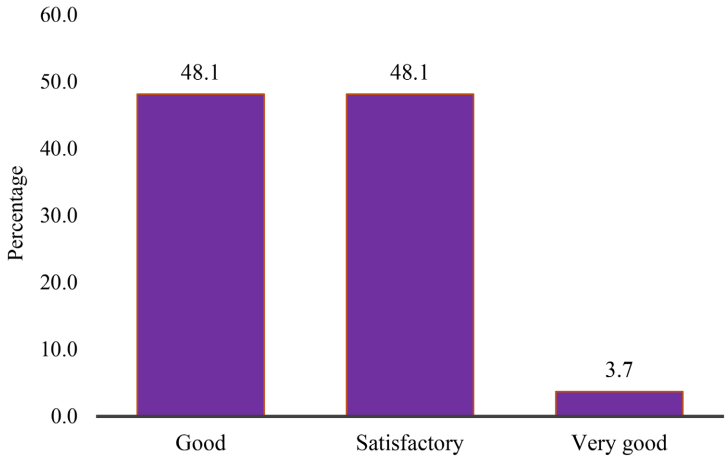

Figure 8. Bar chart presenting the distribution of study subjects according to the Patient's Global assessment of quality of life.

5. Discussion

Several clinical studies have demonstrated the effectiveness of Iron (III) Hydroxide Polymaltose Complex (IPC) in improving haemoglobin levels in patients with iron deficiency anaemia (IDA) [10] [11]. Our study is consistent with existing evidence and reinforces the effectiveness of iron supplementation in treating IDA during pregnancy. The significant increase in haemoglobin levels observed after a four-week intervention with IPC (Hemoforce Gravida) aligns with findings from prior clinical studies.

A study by Abdelazim *et al.* reported that ferric hydroxide polymaltose significantly improved haemoglobin levels, erythrocyte indices, and serum ferritin in pregnant women with IDA [10]. Similarly, Geisser demonstrated that IPC is effective in treating IDA due to its favorable pharmacokinetic properties and higher tolerability [11]. In our study, IPC (Hemoforce Gravida) resulted in a clinically meaningful mean haemoglobin increase of 1.45 g/dL *i.e.* 15% rise within four weeks. These findings are consistent with the literature indicating that iron supplementation can produce rapid haematological improvement, which is critical given the association of untreated anaemia with adverse outcomes such as preterm birth, low birth weight, and increased maternal morbidity.

In addition to effectiveness, our findings highlight the favorable tolerability profile of IPC. IPC formulations are known to have improved gastrointestinal tolerability compared to conventional iron salts [11] [12]. Unlike ferrous salts, which are commonly associated with gastrointestinal adverse effects such as constipation and abdominal discomfort, IPC demonstrates better patient acceptance and compliance [12]. Furthermore, IPC can be administered with food without signifi-

cantly compromising absorption, which enhances its practicality in real-world settings [11].

Adherence to iron supplementation remains a major challenge in Sub-Saharan Africa. Factors such as limited awareness, poor access to antenatal care, cost constraints, side effects, and inadequate counselling contribute to poor compliance. A Demographic and Health Survey (DHS) conducted in Angola (2015-2016) reported that only 34.7% of pregnant women adhered to iron supplementation for at least 90 days [13].

In contrast, our study demonstrated relatively high adherence to IPC (Hemoforce Gravida), with 67.7% of participants achieving high adherence. This observation is supported by findings from Saha *et al.*, who reported better adherence and tolerability with IPC compared to ferrous sulfate in pregnant women [12]. The improved tolerability profile of IPC likely contributed to better compliance in our study population. These findings underscore the importance of selecting iron formulations that optimize both efficacy and patient adherence.

Gastrointestinal adverse effects remain a key limitation of conventional oral iron therapy. Studies by Sunkara *et al.* and Hashash *et al.* have demonstrated that iron salts such as ferrous sulfate can cause gastritis and mucosal injury due to localized oxidative effects [14] [15]. In contrast, IPC formulations are associated with fewer gastrointestinal complications [9]. In our study, 50% of participants had previously discontinued other iron supplements due to gastrointestinal intolerance. The improved tolerability of IPC (Hemoforce Gravida) contributed to better adherence and was associated with significant improvements in haemoglobin levels and patient-reported symptoms such as fatigue and headache, ultimately enhancing quality of life.

Adequate iron status during pregnancy is critical, particularly during the second and third trimesters when iron requirements are highest [2]. Burke *et al.* emphasized the importance of maintaining optimal maternal iron levels to reduce the risk of adverse perinatal outcomes [9]. Bothwell also highlighted that increased maternal blood volume and fetal demands significantly elevate iron requirements during later stages of pregnancy [2]. Our findings are consistent with this evidence, as the majority of participants (54.0%) were in the second trimester, a period characterized by heightened iron demand. This underscores the importance of timely and effective iron supplementation strategies.

The effectiveness observed with Hemoforce Gravida suggests that its formulation and bioavailability may offer advantages over conventional iron preparations. The rapid improvement in haemoglobin levels indicates efficient iron absorption and utilization. This is particularly relevant in resource-limited settings, where access to comprehensive antenatal care and nutritional support may be limited.

In summary, Hemoforce Gravida demonstrated effectiveness, good tolerability, and improved adherence in the management of iron deficiency anaemia during pregnancy. These findings support its potential role as a practical therapeutic option in antenatal care, particularly in regions with a high burden of anaemia. Fur-

ther studies are warranted to evaluate long-term outcomes, optimal dosing strategies, and its integration into standardized maternal health programs.

6. Study Limitation

This study has several limitations that should be considered when interpreting the findings. The single-arm, before-and-after design lacks a concurrent control group, which limits the ability to attribute observed effects solely to the intervention and introduces the potential for confounding factors and temporal biases. The relatively short follow-up period further restricts the assessment of long-term efficacy and sustainability of outcomes. In addition, the loss of 11 participants may have introduced attrition bias, potentially affecting the robustness and generalizability of the results. Therefore, any claims of comparative superiority should be interpreted with caution, and confirmation through well-designed randomized controlled trials with longer follow-up is warranted.

7. Conclusions

The present study involving 189 pregnant women supplemented with Iron (III) Hydroxide Polymaltose syrup demonstrated a significant increase in haemoglobin by 15% within 28 days. This result indicates that supplementation positively impacted hemoglobin levels among the evaluated pregnant women, which is crucial for maternal and fetal health.

The findings suggest that Iron (III) Hydroxide Polymaltose syrup may be an effective option for preventing and treating gestational anemia, contributing to improved pregnancy outcomes. Future studies are recommended to investigate long-term effectiveness, possible side effects, and comparisons with other available interventions.

Supplementation with Iron (III) Hydroxide Polymaltose syrup represents a promising advance in the management of anemia in pregnant women, highlighting the importance of appropriate nutritional interventions during pregnancy.

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Conflicts of Interest

The author confirms that the study was conducted in accordance with applicable ethical standards, and that the interpretation of data and final manuscript content were carried out with scientific integrity and without undue influence.

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