**Ferric Polymaltose Complex in Treatment of Iron Deficiency and Iron Deficiency Anemia with Pregnancy**

**ABSTRACT**

**Background:** Iron deficiency anemia associated with adverse maternal and neonatal outcome.

**Objectives:** To evaluate the efficacy of the ferric hydroxide polymaltose (FPM) tablets in treatment of iron deficiency (ID) and iron deficiency anemia (IDA) with pregnancy.

**Material and Methods:** One hundred and twenty-two women with ID (ferritin <15 ug/l) and IDA (hemoglobin ≤10 gm/dl) during pregnancy will be included in this study. Studied women will be treated with FPM tablets for 3 months. The pre-treatment ferritin, hemoglobin, RBCs-corpuscular volume and hemoglobin (MCV and MCH) will be compared by the post-treatment values to detect the efficacy of FPM in treatment of ID and IDA with pregnancy.

**Key words:** FPM, Iron, Deficiency, Anemia, Pregnancy.

**Introduction**

Hemoglobin <11 gm/ dl defined as anemia and iron deficiency anemia (IDA) is the commonest type of nutritional deficiencies [1-2].

The iron requirements increase during the second and third trimesters of pregnancy [3]. In addition; the blood loss during deliveries increases the maternal anemia [4-5] and maternal anemia is a leading cause of adverse perinatal outcome [6-9].

Recently; ***Froessler et al,*** reported that the ID and its related anemia associated with adverse outcome as reduced maternal cognitive activities and increased maternal depressive disorders.

***Froessler et al,*** reported the preterm delivery and intra-uterine growth restriction as adverse neonatal outcome for ID and IDA [10].

Peri-partum anemia increases the need for red blood cells (RBCs) transfusion [11-12] and the RBCs transfusion corrects hemoglobin and not the underlying cause [13]. Iron supplementation is crucial during pregnancy to reduce the adverse perinatal outcome related to ID and IDA [14].

Oral iron therapy is an effective option for treatment of ID and IDA. The iron salts cause gastric discomfort and constipation which adversely affect the compliance [15-16].

The Ferose® tablets contains tolerable, chocolate flavor, non-ionic iron in form of ferric hydroxide-polymaltose complex (FPM), which improves the compliance and ensures continuous iron intake [17]. In addition; the adverse gastro-intestinal troubles less frequently reported with FPM compared to the iron salts [18-19]. So, the current study designed to evaluate the efficacy of the FPM tablets in treatment of ID and IDA with pregnancy.

Primary outcome measures; the efficacy of the FPM tablets in treatment of ID and IDA with pregnancy. Secondary outcome measures; the tolerability and the side effects related to the FPM tablets.

**Material and methods**

This study will be conducted over 6 months during the year 2019; after approval of the study by the local Obstetrics and Gynecology department Ethical Committee and patients` consent.

One hundred and twenty-two women with ID (ferritin <15 ug/l) and IDA with pregnancy (hemoglobin (≤10 gm/dl (7-10 gm/dl mild to moderate)) will be included in this study.

Diagnosis of ID based on serum ferritin (ug/l) and IDA based on; serum ferritin (ug/l), hemoglobin concentration (gm/dl), RBCs-mean corpuscular volume (MCV) and hemoglobin (MCH). [20].

Studied women will be treated with the FPM tablets for correction of ID and IDA with for 3 months.

Inclusion criteria include; pregnant women ≥ 20 years old, 14-26 weeks` gestation with serum ferritin <15 ug/l and hemoglobin ≤10 gm/dl.

Pregnant women with intolerance or hypersensitivity to oral iron and/or anemia other than IDA and/or received blood transfusion during current pregnancy will be excluded from this study.

Studied women will be treated with the FPM tablets for correction of ID and IDA with pregnancy three times daily (30 mg of iron required daily during pregnancy) for 3 months.

The ferric iron of the FPM is absorbed in the [duodenum](https://en.wikipedia.org/wiki/Duodenum) and [jejunum](https://en.wikipedia.org/wiki/Jejunum) via an active controlled mechanism and the iron content of the FPM reaches the blood bound to [transferrin](https://en.wikipedia.org/wiki/Transferrin) (no unbound iron reaches the blood) then stored in the liver as ferritin which will be available for hemopoiesis [18].

The maximum absorption capacity of the iron content of the FPM tablets reached 30 minutes after the oral intake of the Ferose® tablets and continuously increased over 24 hours [21].

About 10-15% of the iron content of the FPM absorbed after the oral intake of Ferose® tablets (10-15 mg is absorbed from 100 mg FPM tablets) [22].

Studied women will receive oral folic acid with FPM tablets to avoid folic deficiency and participants will be asked during each ante-natal care visit for the side effects related to FPM tablets as metallic taste and/or gastrointestinal intolerance.

The pre-treatment ferritin, hemoglobin, RBCs-mean corpuscular volume (MCV) and hemoglobin (MCH) will be compared by the 3 months` post-treatment values to detect the efficacy of the FPM in treatment of ID and IDA with pregnancy [23,24].

Primary outcome measures; the efficacy of the FPM tablets in treatment of ID and IDA with pregnancy. Secondary outcome measures; the tolerability and the side effects related to the FPM tablets.

**Statistical Analysis**

Collected data will be analyzed using Statistical Package for Social Sciences (SPSS) version 20 (Chicago, IL, USA). The mean and standard deviation (±SD) will be used to present the numerical values, while the number (n) and percentage (%) will be used to present the categorical values. Student (t) test will be used to compare the pre-treatment ferritin, hemoglobin, RBCs-MCV and MCH by the 3 months` post-treatment values to evaluate the efficacy of FPM in treatment of ID and IDA with pregnancy. *P*-value <0.05 considered significant.

**Ethics approval and consent:** The study will be approved by the local departmental ethical committee of the hospitals and informed consent will be taken from the women before inclusion in this study.

**Competing interests:** Authors declare no conflict of interest related to this article.

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