

Date: 9 December 2018

To whom my concern

The Acting head of the Obstetrics and Gynecology department of Ahmadi hospital approved the conduction of the study entitled; **Ferric Polymaltose Complex in Treatment of Iron Deficiency and Iron Deficiency Anemia with Pregnancy** under supervision of **Professor Ibrahim A. Abdelazim** in Ahmadi hospital during the period of **May 2019 till December 2019** after informed consent of the studied women. Studied women with iron deficiency (ferritin <15 ug/l) and iron deficiency anemia with pregnancy (hemoglobin (≤ 10 gm/dl (7-10 gm/dl mild to moderate)) will be included in this study.

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

Studied women will be treated with the ferric hydroxide-polymaltose complex (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.

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. 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 (primary outcome).


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