

To whom my concern

The heads of the Obstetrics and Gynecology departments of West Kazakhstan Medical University (WKZMU) No.¹ and Ahmadi hospital, Kuwait Oil Company (KOC), Kuwait, approved the conduction of the study entitled; **Heme-bound iron (Optifer[®]) versus intravenous iron (Ferosac[®]) in treatment of pregnancy associated iron deficiency anemia**, in the Obstetrics and Gynecology departments of West Kazakhstan Medical University (WKZMU) and Ahmadi Hospital, Kuwait Oil Company (KOC), Kuwait.

The study is comparative study and will be conducted in the Obstetrics and Gynecology departments No.¹ of WKZMU and Ahmadi hospital, KOC, Kuwait from June 2019 till December 2019; to compare the efficacy and tolerability of the heme-bound iron (HIO) Optifer[®] versus iron saccharate complex (Ferosac[®]) in treatment of pregnancy associated iron deficiency anemia (IDA).

Pregnant women with pregnancy associated iron deficiency anemia (IDA) and hemoglobin ≤ 10 gm/dl (8-10 gm/dl) will included in this study after informed consent. Studied women will receive either HIO (Optifer[®]) tablets (PO group) or intravenous iron saccharate (Ferosac[®]), (IV group) for correction of pregnancy associated IDA.

Inclusion criteria includes; pregnant women ≥ 20 years old, 14-26 weeks' gestation, with hemoglobin ≤ 10 gm/dl (8-10 gm/dl). Pregnant women with anemia other than iron deficiency anemia (IDA) and/or received blood transfusion during current pregnancy will excluded from this study.

Women in the PO group will receive HIO (Optifer[®]) tablets twice daily (1 tablet morning and 1 tablet evening) not related to meals for ≥ 3 months till hemoglobin level of 11-12 gm/dl then one tablet daily as maintenance dose. Women in the Intravenous (IV) group will receive the calculated intravenous iron dose according to the formula; total iron needed in mg = $2.4 \times$ pre-pregnancy weight in kg \times (target hemoglobin concentration - actual hemoglobin concentration) gm/dl + 500 mg. The aim of the study is to compare the efficacy and tolerability of the heme-bound iron (HIO) Optifer[®] versus iron saccharate complex (Ferosac[®]) in treatment of pregnancy associated iron deficiency anemia (IDA).

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