



## Case Report

### Ferrous Sulphate In Comparison to Lactoferrin in Managing Anemia in Gestation

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#### Abstract

**Aim:** The aim was to compare the effectiveness of ferrous sulphate to lactoferrin in managing anemia with gestation.

**Materials and methods:** This is a prospective randomized, parallel-group, single-center study was conducted in the Obstetrics and Gynecology Aljazeera Hospital from April 2017 till May 2018, Egypt and included a total of 400 pregnant lady in the second trimester who were enrolled and randomly distributed either to receive 150 mg of dried ferrous sulphate capsules or lactoferrin 250 mg capsules once daily for 12 weeks. The primary efficacy parameter was the amount of increase in hemoglobin concentration by 4 and 8 weeks, the adverse effects related to iron therapy and the patient compliance to the treatment.

**Results:** In the present study, there was a net increase in hemoglobin after 8 weeks as a result of receiving lactoferrin in comparison to ferrous sulfate with a statistically significant P value ( $p < 0.001$ ).

**Conclusion:** Supplementation with Lactoferrin has better result than ferrous sulfate in pregnant females that had anemia with gestation in elevating hemoglobin level and has lesser GIT upset and better compliance.

#### Introduction

Iron Deficiency Anemia (IDA) happens when the iron fails to meet up normal red blood cell manufacture and is considered the most frequent cause of anemia [1]. The incidence of anemia in the developing countries ranges from thirty-five to seventy five percent. [2] Oral iron is present the most commonly available are ferrous sulphate and ferric forms. Most of these preparations differ in their, effectiveness, adverse outcome and bioavailability [3].

Lactoferrin is a glycoprotein, and a member of a transferrin family that is related to the proteins that has the ability to bind and transfer iron. [4] HB level could be estimated using spectrophotometry [5].

#### Patients and methods

The study protocol and complications were fully explained to all participants and a written informed consent was taken before participation in the study. Eighty patients were required in each group for the study to have 90% power to detect 10% difference

between two groups regarding success rate ( $p = 0.05$ , two-sided). To compensate for possible non-evaluable data, we enrolled 200 participants in each group. A total of 414 pregnant women were enrolled and randomly assigned into two study groups using a computerized random number generator in a sequence of sealed, numbered opaque envelopes, with a 1:1 randomization ratio. 14 patients were dropped out (6 discontinued drug intake and 8 lost follow-up).

A total of 400 pregnant women completed the study. The patients were assigned to take the medication orally, once daily after lunch. Patients were advised to avoid the intake of tea, coffee, milk, milk products, antacids and calcium preparation within 2 h before or after iron capsules. Group 1 (Lactoferrin group): included 200 pregnant women who received lactoferrin 250 mg capsules (Jarrow Formulas, Egypt) once daily for eight consecutive weeks. Group 2 (Ferrous group): included 200 pregnant women who received 150 mg of dried ferrous sulphate capsules (Ferrofol capsules, EIPICO, Egypt) once daily for twelve consecutive weeks. Pregnant women with single fetus, in the second trimester, with IDA (hemoglobin

level less than 11 g/dL and ferritin levels less than 25ng/dL) were enrolled.

Women with a history of anemia due to any other causes, such as chronic blood loss, hemolytic anemia and thalassemia (including thalassemic trait), severe anemia requiring blood transfusion, bronchial asthma, clinical and/or laboratory evidence of hepatic, renal, hematologic or cardiovascular abnormalities, history of peptic ulcer, hypersensitivity to iron preparations and treatment with any other iron preparation in the last one month before study entry and suspected acute infection were excluded from the study.

The primary outcome was the amount of increase in hemoglobin concentration by 4 and 8 weeks, the adverse effects (the patients were asked to report any unaccepted symptoms during the study period) related to iron treatment and the patient compliance to treatment. Obstetric outcome in terms of gestational age at delivery, mode of delivery, maternal complications (postpartum hemorrhage and defective lactation) and neonatal outcome (neonatal weight, admission to neonatal intensive care unit and neonatal death defined as death in the first four weeks after birth) were assessed as a secondary outcome.

### Statistical methods

Statistical analysis Data were collected, tabulated, statistically analyzed by computer using SPSS version 16 (SPSS Inc., Chicago, IL), two types of statistics were done: Descriptive statistics Quantitative data are expressed to measure the central tendency of data and diversion around the mean, Mean (x) and Standard Deviation (SD). Analytic statistics Chi-Square (x2) and t-test were used to compare two groups. All these tests were used as tests of significance at p value 0.05 was considered statistically nonsignificant. p value 0.05 was considered statistically significant. p value 0.001 was considered statistically highly significant.

### Results (Tables 1-3)

	(Lactoferrin group)	(Ferrous group)	p value
Age	23.5±6.19	23.6±6.66	>0.05*
Parity	1.62±2.38	1.70±2.30	>0.05
GA at inclusion	18.42±2.79	18.11±2.84	>0.05
BMI at inclusion	22.88±3.97	22.92±3.93	>0.05
No of ANC visits	2.06± 4.22	2.18± 4.16	>0.05

Table 1: Demographic data

	(Lactoferrin group)	(Ferrous group) t	t-test	p value
Level of Hemoglobin at start	8.1 ± 0.61	8 ± 0.699	1.553	>0.05
Hemoglobin level After 4 weeks	9.46 ± 0.42	8.7 ± 0.722	13.306	<0.001*
Hemoglobin level After 8 weeks	10.52± 0.29	9.23 ± 0.633	25.430	<0.001
Net increase in hemoglobin	2.42 ± 0.52	1.23 ± 0.23	29.281	<0.001

Table 2: Hb level (gm/dL) before and after treatment.

	(Lactoferrin group)	(Ferrous group)	Chi square	p value
GIT complications	20	120	109.980	<0.001*
Abdominal pain	40	120	66.667	<0.001
Vomiting	20	60	25	<0.001
Constipation	40	120	66.667	<0.001
Dark stools	0	60	70.588	<0.001
Want to stop intake	0	40	44.444	<0.001

Table 3: demonstrates the adverse effects with iron use.

### Discussion

Previous researches revealed inconclusive data showing improvement or decreasing iron absorption. [6-8] In the present study, there was a net increase in hemoglobin after 8 weeks as a result of receiving lactoferrin in comparison to ferrous sulfate with a statistically significant P value (p<0.001). Recently, a randomized trial that included three hundred ladies at different trimesters of gestation orally administered ferrous sulfate or thirty percent iron-saturated bovine lactoferrin, revealed an increased hemoglobin and total serum iron concentrations in ladies who received bovine lactoferrin than in women who received ferrous sulfate with the absence of adverse effects [9]. Also, in the current study, the GIT complications occurred more frequently with the ferrous sulphate receiving pregnant ladies with a statistically significant P value (p < 0.001).

While in the current study, the number of ladies who asked to replace the medication was greater in the ferrous sulphate using

patients with a statistically significant P value ( $p < 0.001$ ). In a previous study made by Mohamed Rezk, et al 2015, they concluded that lactoferrin increased hemoglobin level more than ferrous sulphate in pregnant females who had anemia with gestation with lesser side effects [10].

In the current study, in correspondence to the data revealed supplementation with Lactoferrin has better result than ferrous sulfate in pregnant females that had anemia with gestation in elevating hemoglobin level and has lesser GIT upset and better compliance. But, future researches must be made to reach more conclusive data.

## Conclusion

Supplementation with Lactoferrin has better result than ferrous sulfate in pregnant females that had anemia with gestation in elevating hemoglobin level and has lesser GIT upset and better compliance.

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