Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Iron supplement use on pregnancy outcomes in women without iron deficiency referred to Hazrat zeynab and Hafez gynecology clinic in 2016

Protocol summary

Summary

Considering the iron supplementation during pregnancy and the problems due to over using of this supplementation, almost all women take iron supplementation during pregnancy. The aim of this study was to determine the effect of the iron supplementation prophylactic on outcome and the problems of pregnancies. This clinical trial study among 90 healthy pregnant women with aimed to effect of Iron supplement use on pregnancy outcomes in women without iron deficiency. Inclusion criteria: Age between 18 to 40 years without any underlying condition such as diabetes, hypertension, liver disease and kidney disease, heart disease and vascular, no history of pregnancy complications included preeclampsia, gestational diabetes, premature labor, miscarriage, stillbirth and low birth weight in previous pregnancies, no risk factors for pre-eclampsia, gestational diabetes and IUGR. Exclusion criteria: younger than 18 and older than 40 years, having a risk factor for preeclampsia, gestational diabetes and IUGR, diabetes, obesity, multiple pregnancy, cardiovascular disease, kidney disease, connective tissue disease and history of preeclampsia in a previous pregnancy, having a history of pregnancy complications in previous pregnancies. Three groups as follows: 1. Group A: Pregnant women who fit their iron stores (serum ferritin level <30 ppm) and typically take ferrous sulfate. 2. The second group of pregnant women with thalassemia minor levels of serum ferritin them more than 30 micrograms per liter is needed to get pills of iron supplements are pregnant women that the serum ferritin is greater than 30 micrograms per deciliter is and because of intolerance to oral ferrous sulfate (gastrointestinal symptoms such as nausea, bloating and constipation), do not use supplements 3. The third group of pregnant women that their ferritin level of less than 30 micrograms per deciliter of iron deficiency and iron supplements they consume. After determining the three groups, clinical trial results, including hemoglobin, serum ferritin level, MCV, MCH and serum iron levels in the quarter, measured and reported. During pregnancy, any complication associated with pregnancy in all groups were recorded and compared. In the other study outcomes and complications of pregnancy, including preeclampsia, gestational diabetes, premature labor, miscarriage, stillbirth, type of delivery, gestational age, low birth weight and will be recorded and reported.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051533976N1**
Registration date: **2017-06-03, 1396/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor Of Research, Shiraz University of Medical Sciences

Expected recruitment start date
2017-03-20, 1395/12/30
Expected recruitment end date
2018-02-19, 1396/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Iron supplement use on pregnancy outcomes in women without iron deficiency referred to Hazrat zeynab and Hafez gynecology clinic in 2016

Public title
Iron supplementation in pregnancy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Age between 18 to 40 years without any underlying condition such as diabetes, hypertension, liver disease and kidney disease, heart disease and vascular, no history of pregnancy complications included preeclampsia, gestational diabetes, premature labor, miscarriage, stillbirth and low birth weight in previous pregnancies, no risk factors for pre-eclampsia, gestational diabetes and IUGR. Exclusion criteria: younger than 18 and older than 40 years, having a risk factor for preeclampsia, gestational diabetes and IUGR, diabetes, obesity, multiple pregnancy, cardiovascular disease, kidney disease, connective tissue disease and history of preeclampsia in a previous pregnancy, having a history of pregnancy complications in previous pregnancies.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz
City
Shiraz
Postal code
Approval date
2017-04-19, 1396/01/30
Ethics committee reference number
IR.SUMS.MED.REC.1396.21

Health conditions studied

1

Description of health condition studied
Iron deficiency anemia in pregnancy
ICD-10 code
D50.8
ICD-10 code description
Other iron deficiency anaemias

Primary outcomes

1

Description
Hemoglobin level
Timepoint
At first, seconed and third trimister pregnancy
Method of measurement
Laboratory

2

Description
Serum ferritin level
Timepoint
At first, seconed and third trimister pregnancy
Method of measurement
Laboratory

3

Description
MCV level
Timepoint
At first, seconed and third trimister pregnancy
Method of measurement
Laboratory

4

Description
MCH level
Timepoint
At first, seconed and third trimister pregnancy
Method of measurement
Laboratory

5

Description
Serum iron level
Timepoint
At first, seconed and third trimister pregnancy
Method of measurement
Laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Group A: Pregnant women who fit their iron stores (serum ferritin level <30 ppm) and typically take 60 mg/day ferrous sulfate.
Category
Treatment - Drugs

2

Description
The second group of pregnant women with thalassemia minor levels of serum ferritin them more than 30 micrograms per liter is needed to get pills of iron supplements are pregnant women that the serum ferritin is greater than 30 micrograms per deciliter is and because of intolerance to oral ferrous sulfate (gastrointestinal symptoms such as nausea, bloating and constipation), do not use supplements
Category
Treatment - Drugs

3

Description
The third group of pregnant women that their ferritin level of less than 30 micrograms per deciliter of iron deficiency and 60 mg/day iron supplements they consume.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez & Hazrat Zienab hospital
Full name of responsible person
Lilya Abassi
Street address
Shiraz University of Medical Sciences، Zand Street، Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Leilyia Abassi
Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty