Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

gastrointestinal complications of iron supplement in pregnant women

Protocol summary

Summary
Introduction and Background: Numerous researches have shown that the consumption of ferrous sulfate pills in non-pregnant women causes gastrointestinal complications. Furthermore, pregnancy itself causes changes in gastrointestinal system and induces gastrointestinal disorders. Objectives: Evaluation of ferrous sulfate side effects in pregnant women with Hb>13.2gr/dl. Design: This is a double-blind clinical trial research. Participants: 139 pregnant women with Hb>13.2gr/dl. 88 persons were placed in the case group and 51 in the control group. Intervention: In the case group, individuals consumed one ferrous sulfate pill containing 50 mg iron, per day, from the 20th week to the end of pregnancy. The control group consumed one placebo tablet per day from the 20th week to the end of pregnancy. Main outcome measures: The side effects of iron and placebo were investigated in the 24th and 36th weeks of gestation.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT138807182558N1**
Registration date: **2003-06-22, 1382/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2003-06-22, 1382/04/01

Registrant information
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Recruitment status
Recruitment complete
Funding source
Researcher

Expected recruitment start date
2003-06-22, 1382/04/01
Expected recruitment end date
2005-06-21, 1384/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
gastrointestinal complications of iron supplement in pregnant women

Public title
gastrointestinal complications of iron supplement in pregnant women
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age 17-35, Hb>13.2 gr/dl in 13- 18 W of gestation, single gestation, BMI=19.8 -26, no smoking and alcohol, appropriate nutrition, exclusion criteria: history or illness in heart disease. lung disease, kidney disease, gastro intestinal, thyroid, parathyroid, pancreas, diabetes mellitus, diabetes, gestational diabetes, lupus, chronic hypertension, epilepsy, viral infection, toxoplasmosis, STD, polycytemia vera, history and acute disease of malignancy, hyperemesis gravidarum, threatened abortion, bleeding in pregnancy
Age
From **17 years** old to **35 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **139**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tarbiat Modaress University
Street address
Jalale-ale-ahmad ave,Tehran
City
Tehran
Postal code
Approval date
2004-03-16, 1382/12/26
Ethics committee reference number
103/6230

Health conditions studied

1

Description of health condition studied
Normal pregnancy
ICD-10 code
Z34
ICD-10 code description
Supervision of normal pregnancy

2

Description of health condition studied
Iron supplementation in pregnant women
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Assesment of gastrointestinal side effects of Iron tablets
Timepoint
24th and 36th weeks of gestation
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one ferrous sulfate pill containing 50 mg iron, per day, from the 20th week to the end of pregnancy
Category
Treatment - Drugs

2

Description
Control group: One placebo tablet per day from the 20th week to the end of pregnancy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Maryam Hospital
Full name of responsible person
Pregnant women
Street address
Shoosh SQ
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat modarres university
Full name of responsible person
Vice Chancellor for research
Street address
Jalal ale ahmad AVe, Tehran
City
Tehran
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat modarres university
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
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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