

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Esmat Jafarbegloo

Name of organization / entity

Qom university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 1722 5100

Email address

jafarbegloo@muq.ac.ir

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, polycythemia 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

Name of organization / entity
TMU

Full name of responsible person
Esmat Jafarbegloo

Position
MSC Midwifery

Other areas of specialty/work

Street address
Jalal alahmad AVE, Tehran

City
Tehran

Postal code

Phone
+98 21 2255 7378

Fax

Email
jafarbegloo_2004@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
TMU

Full name of responsible person
Esmat Jafarbegloo

Position
MSC Midwifery

Other areas of specialty/work

Street address
Jalal al ahmad AVE, Tehran

City
Tehran

Postal code

Phone
+98 21 2255 7378

Fax

Email
jafarbegloo_2004@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
TMU

Full name of responsible person
Esmat Jafarbegloo

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+98 21 2255 7378

Fax

Email
jafarbegloo_2004@yahoo.com

Web page address

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