Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

A randomized placebo-controlled trial to determine the effect of iron supplementation on hematological indices in pregnant women with hemoglobin ≥13.2 g/dl

Protocol summary

Summary

The objective of our study is to investigate the effect of iron supplementation on hematological indices in pregnant women with hemoglobin more than or equal to 13.2 g/dl. In a randomized, double-blind, placebo-controlled trial eighty-seven pregnant women with Hb≥13.2 g/dl and ferritin≥14.3g/dl were selected with gestational age 13-18 weeks. Each woman received either 50 mg ferrous sulfate daily or placebo during pregnancy. Hb, HCT, MCV, MCH, MCHC, and RBC were measured in 24-28 and 32-36 gestational weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710181531N1**
Registration date: **2009-11-08, 1388/08/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-11-08, 1388/08/17

Registrant information

Name

Zeinab Hamzehgardeshi

Name of organization / entity

Tarbiat Modarres University

Country

Iran (Islamic Republic of)

Phone

+98 15 1324 6883

Email address

hamzeh@razi.ac.ir

Recruitment status

Recruitment complete

Funding source

Tarbiat Modarres University

Expected recruitment start date

2002-03-20, 1380/12/29

Expected recruitment end date

2003-03-20, 1381/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized placebo-controlled trial to determine the effect of iron supplementation on hematological indices in pregnant women with hemoglobin ≥13.2 g/dl

Public title

A randomized placebo-controlled trial to determine the effect of iron supplementation on hematological indices in pregnant women with hemoglobin ≥13.2 g/dl

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with Hb ≥ 13.2 g/dl in the early stage of the second trimester, body mass index (BMI) between 19.8 and 26 kg/m2, single pregnancy, age between 17 and 35 years Exclusion criteria: Falling Hb to less than 10.5 g/dl in the second trimester or 11 g/dl in the third trimester, history of any renal, hepatic, thyroid, or cardiac diseases, presence of diabetes, asthma, hypertension, or inflammatory diseases, presence of severe nausea and vomiting of pregnancy, smoking, substance abuse, history of threatened abortion

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: **87**
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 Modarres University
Street address
Gisha, Jalale Ale Ahmad highway, Tehran.
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
103/5364

Health conditions studied

1

Description of health condition studied
Pregnant women of high hemoglobin
ICD-10 code
O28.0
ICD-10 code description
Abnormal haematological finding on antenatal screening of mother

Primary outcomes

1

Description
Hematologic indices
Timepoint
Baseline, at gestational weeks 24 -28 and 32-36
Method of measurement
Cell Blood Count with sismex k1000

Secondary outcomes

empty

Intervention groups

1

Description
Ferrous sulfate, 150 mg tablet with 50 mg ferrous elemental, daily, from 20th gestational week to the end of pregnancy
Category
Prevention

2

Description
Placebo tablets, one tablet daily, from 20th gestational week to the end of pregnancy
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Street address
North Karegar Ave., Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Baghiatollah hospital
Full name of responsible person
Street address
Wanak, Mollasadra Ave
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
Gisha, Jalale Ale Ahmad highway, 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

Tarbiat Modarres University,Tehran University medical science

Full name of responsible person

Zeinab Hamzehgardeshi

Position

Ph.D student

Other areas of specialty/work

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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