# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 scientific inquiries

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## Person responsible for updating data

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**Position**

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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*