

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of iron supplementation on iron status markers in pregnant women with High Hemoglobin

Protocol summary

Summary

In a randomized, double-blind, placebo-controlled trial, 83 pregnant women with hemoglobin > 13.2 g/dl and ferritin > 15 µg/l between the 16th and 20th week of pregnancy are randomized into case and control groups. From the 20th week until the end of pregnancy the case group receive one ferrous sulfate tablet containing 50 mg elemental iron daily, while the control group receive placebo. Hemoglobin and ferritin levels at 37-39 weeks of pregnancy are measured and compared. the aim of this study is the relife of pregnancy outcome in pregnant women with high hemoglobin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020612383N1**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name

Leila Alizadeh niari

Name of organization / entity

Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University, Ardabil branch.

Expected recruitment start date

2014-06-21, 1393/03/31

Expected recruitment end date

2014-09-22, 1393/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of iron supplementation on iron status markers in pregnant women with High Hemoglobin

Public title

The effect of iron supplementation in pregnant women with high hemoglobin

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria were being between 18 and 35 years of maternal age; having a body mass index between 19.8 and 26 kg/m², Hb > 13/2 g/dl, fr > 15 µg/l and having a singleton pregnancy. Exclusion criteria were smoking; having a disease related to polycythemia; such as asthma or chronic renal diseases, malignancy and preterm delivery.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**
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
Islamic Azad Universiy
Street address
Islamic Azad universiy, Ardabil branch, Basij square,
Ardabil
City
Ardabil
Postal code
Approval date
2013-05-27, 1392/03/06
Ethics committee reference number
02-12/1124

Health conditions studied

1
Description of health condition studied
high hemoglobin
ICD-10 code
E90
ICD-10 code description
Nutritional and metabolic disorders in diseases classified
elsewhere

Primary outcomes

1
Description
iron status markers
Timepoint
before intervention, 20 weeks later
Method of measurement
evaluation of hb and ferritin levels

Secondary outcomes

1
Description
anemia
Timepoint
the end of pregnancy
Method of measurement
chek of Hb & ferritin

Intervention groups

1
Description
Iron suplementation in pregnant women with high
hemoglobin
Category
Prevention

2
Description
use of plasebo of iron in preganant women with high
hemoglobin
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Prenatal Care Clinics
Full name of responsible person
Agayi Masome
Street address
City
Ardabil

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Ardabil branch, Islamic Azad University
Full name of responsible person
Mr Hashemian
Street address
Ardabil branch, Islamic Azad University, Hafez square,
Ardabil
City
Ardabil
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Ardabil branch, Islamic Azad 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

Ardabil branch, Islamic Azad University

Full name of responsible person

Alizadeh Leila

Position

faculty

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

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Position

MS

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Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

dr Mani Ramzi

Position

hematologist

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Shiraz University of Medical Sciences, Namazi square,
Shiraz, Iran

City

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