Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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>15µg/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)
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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 26kg/m2, Hb>13/2g/dl,fr>15µg/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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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