

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison effect of daily versus intermittent dose of iron supplement on the blood indices, serum level of iron, ferritin and zinc in healthy pregnant women

Protocol summary

Summary

This clinical trial study aimed to compare daily and intermittent dose of iron supplementation on blood indices, Iron, Zinc and Ferritin among 146 healthy pregnant women. Inclusion criteria for pregnant women are ages 17- 40, being less than 20 weeks of gestation, having hemoglobin higher than 11 g/dl, and no symptoms of minor β Thalassemia or any other diagnosed internal disease. Furthermore, those with history of abortion or more than 2 deliveries will be excluded from the study. All participants at the first admission in the Gynecology and Obstetrics Clinics will be randomly divided in 2 groups. Initial blood samples (5 ml) will be drawn at 10-14 weeks of pregnancy (first trimester) to control CBC, Fe, Zinc and Ferritin. From 20th weeks of pregnancy Case groups will receive daily dose of iron supplement (50 mg/day) and those in control group will receive intermittent dose of iron supplement (three times /week) (50 mg/each time). Then blood samples will be taken from all subjects at trimester two (26-28 weeks) and three (34-37 weeks) and the results will be compared with the results of trimester one. Additionally, results will be compared between two groups. All the subjects will be monthly followed up regarding consumption of the medication and its side effects.

General information

Acronym

Iron supplementation and pregnancy

IRCT registration information

IRCT registration number: **IRCT2012082810682N1**

Registration date: **2012-10-08, 1391/07/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-08, 1391/07/17

Registrant information

Name

Haydeh Alaoddolehei

Name of organization / entity

Babol University of Medical Sciences

Country

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+98 11 1223 4274

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Recruitment status

Recruitment complete

Funding source

The research council of Babol University of Medical Sciences.

Expected recruitment start date

2012-10-11, 1391/07/20

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of daily versus intermittent dose of iron supplement on the blood indices, serum level of iron, ferritin and zinc in healthy pregnant women

Public title

Effects of different dose of Iron in prevention of anemia

in healthy pregnant women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Healthy pregnant women; Less than 20 weeks of gestation; More than 11 g% hemoglobin level.

Exclusion criteria: People with β minor thalassemia;

Diagnosed internal diseases; Abortion; More than 2 delivery.

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Ganj-afroz Ave.

City

Babol

Postal code

4717641367

Approval date

2012-09-09, 1391/06/19

Ethics committee reference number

7074.30.g.p

Health conditions studied

1

Description of health condition studied

pregnancy

ICD-10 code

O99.0

ICD-10 code description

Anaemia complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Hb

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

coulter counter: g%

2

Description

MCV

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

colter counter: fl

3

Description

RBC

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

colter counter: mil/mm3

4

Description

Iron

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

colorimetric: micg%

5

Description

Ferritin

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

ELISA: ng/ml

6

Description

Zinc

Timepoint

20, 26-28 and 34-37 weeks of gestation

Method of measurement

colorimetric: micg%

Secondary outcomes

empty

Intervention groups

1

Description

control: daily dose of iron supplementation (50 mg/dose) from 20 weeks of gestation

Category

Prevention

2

Description

Case: 3 times of iron supplementation in week (50 mg/dose) from 20 weeks of gestation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology and Obstetrics clinics

Full name of responsible person

Haydeh Alaoddolehei

Street address

Keshavarz Blvd, Ganj-Afroz Ave, Karegar square

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Bijani

Street address

Ganj afroz Ave.

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol University of Medical Sciences

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

Babol University of Medical Sciences

Full name of responsible person

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Position

lab technician

Other areas of specialty/work

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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