Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The effect of supplemental iron elimination on pregnancy outcome

Protocol summary

Summary

The purpose of this clinical trial in Alzahra hospital was to assess the effect of eliminating supplemental iron on pregnancy outcome. A total of Nine hundred sixty healthy women in the first trimester of pregnancy with Hb>12 gr/dl and BP<140/90 mmHg were randomized to receive a multivitamin+30 mg elemental iron or multivitamin + placebo tablet daily from 13th weeks until the end of pregnancy. Iron parameters were analyzed at the 1st trimester and before delivery by using ELISA. Monthly Hb and Hct checkup was performed for placebo group and those with Hb<10.5 gr/dl at the end of the 2nd trimester or Hb<11 at the 3rd trimester were excluded from the study. The outcome of pregnancy, incidence of preeclampsia, preterm labor, premature rupture of membranes and neonatal weight were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101115563N1**
Registration date: **2011-02-24, 1389/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-02-24, 1389/12/05

Registrant information

Name
Elaheh Ouladsahebmadarek
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Email address
madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2005-09-23, 1384/07/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplemental iron elimination on pregnancy outcome

Public title

The effect of supplemental iron elimination on pregnancy outcome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women who were at the first trimester of pregnancy with single fetus, Hb > 12 gr/dl, not receiving iron containing supplements in the last month, BP < 140/90 mmHg, Exclusion criteria: Hb less than 10.5 gr/dl or less than 11 gr/dl at the end of 2nd and 3rd trimesters respectively, miscarriage of current pregnancy, abnormality of the fetus, loss to follow-up

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **960**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht Ave.

City

Tabriz

Postal code

Approval date

2005-07-19, 1384/04/28

Ethics committee reference number

5/4/2665

Health conditions studied

1

Description of health condition studied

pregnancy outcome

ICD-10 code

O26.9

ICD-10 code description

Pregnancy-related condition, unspecified

Primary outcomes

1

Description

preeclampsia

Timepoint

before intervention and every month during pregnancy

Method of measurement

blood pressure checking and urine protein test

2

Description

preterm labor

Timepoint

every month after 20 w of pregnancy

Method of measurement

control of uterine contractions and cervical examination

3

Description

PROM

Timepoint

monthly prenatal care

Method of measurement

declaring membrane rupture by patient and nitrazin test

4

Description

neonatal birth weight

Timepoint

immediately after birth

Method of measurement

by precise scale

Secondary outcomes

1

Description

maternal anemia

Timepoint

monthly prenatal care

Method of measurement

Hb,Hct test

Intervention groups

1

Description

Multivitamin, one oral tablet as well as placebo one tablet, daily, from 13th week of pregnancy until delivery

Category

Treatment - Drugs

2

Description

Multivitamin, one oral tablet as well 30 mg elemental iron, daily, from 13th week of pregnancy until delivery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Prenatal Clinic

Full name of responsible person

Elaheh Ouladsahebmadarek

Street address

Alzahra Hospital, South Artesh Ave., Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Daneshgah St.

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research

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

Tabriz University of Medical Sciences

Full name of responsible person

Elaheh Ouladsahebmadarek

Position

Associate prof. of Ob & Gyn

Other areas of specialty/work

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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