

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

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.

City

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