

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Assessment the effect of zinc supplementation on adverse outcomes of pregnancy, a Randomized Controlled Clinical Trial

Protocol summary

Summary

The aim of this study is to assess the effect of zinc supplement in poor pregnancy outcomes. The inclusion criteria are gestational age between 12-16 weeks, nagative history of high risk pregnancy and maternal underlying diseases. The exclusion criteria are no complete treatment & lack of follow up. Five hundred of pregnant women who refer to private clinics and Alzahra hospital will be included. The women, after giving informed consent, are randomized in two groups (intervention and control). Intervention group will take Folic acid 1 mg from the bigining of pregnancy, ferrous sulfate 30 mg daily from 16th week and zinc 30 mg every other day from 12th week. Control group will take folic acid 1 mg from the bigining of pregnancy and ferrous sulfate 30 mg from 16th week of pregnancy. The pregnancy and delivery will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707161306N1**

Registration date: **2010-04-26, 1389/02/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-04-26, 1389/02/06

Registrant information

Name

Ziba Zahiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

drzibazahiri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice chancellorship-Guilan University of Medical Sciences

Expected recruitment start date

2009-03-02, 1387/12/12

Expected recruitment end date

2011-03-02, 1389/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of zinc supplementation on adverse outcomes of pregnancy, a Randomized Controlled Clinical Trial

Public title

Assessment the effect of zinc supplementation on adverse outcomes of pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Gestetional age of 12-16 weeks based on reliable LMP or first trimester ultrasound, lack of history of high risk pregnancy, lack of chronic underlying diseases (such as heart disease HTN, DM). Exclusion criteria: lack of complete treatment or lack of follow-up

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 500

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research vice chancellorship_Guilan University of
Medical Sciences

Street address

Namjo street

City

Rasht

Postal code

Approval date

2007-02-05, 1385/11/16

Ethics committee reference number

6219

Health conditions studied

1

Description of health condition studied

Adverse outcomes of pregnancy

ICD-10 code

P00.4

ICD-10 code description

Fetus and newborn affected by maternal nutritional
disorders

Primary outcomes

1

Description

congenital defect

Timepoint

postpartum

Method of measurement

neonatal examination

2

Description

birth weight

Timepoint

postpartum

Method of measurement

neonatal weighting

3

Description

preterm labour rate

Timepoint

postpartum

Method of measurement

documented data

4

Description

preeclampsia rate

Timepoint

postpartum

Method of measurement

control of blood pressure

5

Description

chorioamnionitis rate

Timepoint

postpartum

Method of measurement

examination

6

Description

neonatal infection rate

Timepoint

postpartum

Method of measurement

examination

7

Description

postpartum infection rate

Timepoint

postpartum

Method of measurement

examination

8

Description

postpartum hemorrhage rate

Timepoint

postpartum

Method of measurement

examination

9

Description

still birth rate

Timepoint

postpartum

Method of measurement

examination

Secondary outcomes

1

Description

apgar score of 1st , 5th minute

Timepoint

postpartum

Method of measurement

examination

2

Description

duration of pregnancy

Timepoint

postpartum

Method of measurement

documented data

3

Description

neonatal Antropometric measures

Timepoint

postpartum

Method of measurement

examination

4

Description

wieght gain during pregnancy

Timepoint

postpartum

Method of measurement

weighting

Intervention groups

1

Description

zinc 30 mg from 12th week of gestetion every other day
in intervention group

Category

Treatment - Drugs

2

Description

no intervention in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinics and Alzahra hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice chancellorship-Guilan university of
Medical Science

Full name of responsible person

Dr.Abdolrasol Sobhani

Street address

Namjo street

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research vice chancellorship-Guilan university of Medical
Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Ziba Zahiri

Position

Associated professor

Other areas of specialty/work

Street address

Reporoduction Health research center, Alzahra hospital, Namjo st.

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Fax**Email****Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Seyede Fatemeh Dalil Hirati

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

Reproduction health researcher center, Alzahra hospital, Namjo st.

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