Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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
Reasearch 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
documanted 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

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Person responsible for updating data

Contact
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Full name of responsible person
Seyede Fatemeh Dalil Hirati
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Fax
Email
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