Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of copper supplement during pregnancy on premature and pregnancy outcome

Protocol summary

Summary

The purpose of the present study is to evaluate the effect of copper supplementation during pregnancy on the preterm premature rupture of membranes (PPROM), premature rupture of membranes (PROM) and pregnancy outcomes. Study will be conducted as a triple blind randomized clinical trial. The participants (200) will randomly be divided into the 2 groups. In one group copper in a dose of 1000 milligram and in the other group, placebo will be prescribed orally from 16th week of pregnancy. Then the pregnancy outcome including PROM, PPROM, birth weight, placental abruption, placenta previa, hemorrhage during pregnancy, anemia, infection, preterm labor, and preeclampsia will be compared between the 2 groups. Drug adverse effects will be evaluated too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008112624N7**
Registration date: **2010-11-16, 1389/08/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-11-16, 1389/08/25

Registrant information

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Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Iran University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of copper supplement during pregnancy on premature and pregnancy outcome

Public title

Copper prescription in pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: nuliparity, age between 18-35, second trimester of pregnancy, and having written consent. Exclusion criteria: multiple pregnancy, history of any systemic disorders or drug use except iron supplement, known copper sensitivity, polyhydramnios, fetal death, fetal anomalies, smoking, alcohol consumption and drug abuse.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Scieces
Street address
Hemmat Highway, Chamran Cross.
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
896.1

Health conditions studied

1

Description of health condition studied
pregnancy outcome
ICD-10 code
O00-O99
ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
preterm premature rupture of membranes and premature rupture of membranes
Timepoint
9 months
Method of measurement
questionnaire

Secondary outcomes

1

Description
Pregnancy outcome
Timepoint
9 months
Method of measurement
questionnaire

2

Description
birth weight
Timepoint
Delivery
Method of measurement
questionnaire

3

Description
placental abruption, placenta previa, hemorrhage during pregnancy
Timepoint
9 months
Method of measurement
questionnaire

4

Description
anemia
Timepoint
9 months
Method of measurement
Hemoglobin

5

Description
preterm labor
Timepoint
9 months
Method of measurement
questionnaire

6

Description
preeclampsia
Timepoint
9 months
Method of measurement
questionnaire

7

Description
drug adverse effects
Timepoint
9 months

Method of measurement
questionnaire

8

Description
infection
Timepoint
9 months
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Copper tablets, 1000 mg per day from 16th week of pregnancy up to delivery
Category
Prevention

2

Description
Control group: placebo tablets, from 16th week of pregnancy up to delivery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran prenatal care centers
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Iran University of Medical Sciences
Full name of responsible person
Dr. Motavallian
Street address
Hemmat Highway, Chamran Cross.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Iran 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

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Person responsible for updating data

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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