

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of zinc supplementation on prevention of preterm premature rupture of the membranes in high risk pregnant women: a randomized controlled clinical trial

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is to examine the effect of zinc supplementation on prevention of premature rupture of the membranes in high risk pregnant women. In this study, 108 pregnant women aged above 18 years with 16 -20 weeks of gestation, referring to maternal clinics of selected hospitals affiliated in Tehran, who has at least one previous preterm premature rupture of the membranes, will be recruited. Eligible women will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 1:1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 108 will be used for allocation concealment. Each women according to integrated maternal health care program in two weeks (16-20) and (26-30) opacity closed envelope will be given, which contains 84 tablets. Thus intervention group will receive one zinc sulfate (40 mg) tablet daily and control group will receive one placebo tablet daily until delivery. Gestational age during of preterm premature rupture of the membranes will be measured. In addition, checklist about possible complications and daily consumption of tablets will be completed by participants and checklist of information about delivery and birth will be completed by the investigator. The researcher and the participants will be blind about allocation to each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311296709N14**

Registration date: **2014-08-05, 1393/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-05, 1393/05/14

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

mshahnazi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz University of Medical Science

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-02-04, 1393/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc supplementation on prevention of preterm premature rupture of the membranes in high risk pregnant women: a randomized controlled clinical trial

Public title

The effect of zinc supplementation on prevention of preterm premature rupture of the membranes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the history of preterm premature rupture of the membranes at least once in previous pregnancies; singleton pregnancy; normal fetus and amniotic fluid; maternal age 18 years and above; gestational age between 16 and 20 weeks of pregnancy; healthy women without underlying medical condition (cardiac, pulmonary, gastrointestinal, diabetes, epilepsy, hypertension, etc); willingness to participate in the study. Exclusion criteria: the uncertain status of the embryo (abnormal non stress test); any congenital anomalies of the fetus; any complications of pregnancy (history of preeclampsia and current chronic hypertension, bleeding and threatened abortion, nausea and vomiting, etc); having an addiction to drugs and alcohol; taking multivitamin mineral supplementation during pregnancy; severe vaginal infection (with discharge, itching, swelling, erythema, and foul-smelling discharge)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City

East Azarbaijan

Postal code

Approval date

2014-04-28, 1393/02/08

Ethics committee reference number

9316

Health conditions studied

1

Description of health condition studied

Preterm premature rupture of membranes

ICD-10 code

042

ICD-10 code description

Premature rupture of membranes

Primary outcomes

1

Description

Preterm premature rupture of the membranes

Timepoint

20 to 37 weeks

Method of measurement

View sterile Speculum and Nitrazine test

Secondary outcomes

1

Description

Gestational age

Timepoint

Delivery time

Method of measurement

By last menstrual period date and sonography

Intervention groups

1

Description

Intervention group: tablet of zinc sulfate made by faculty of pharmacy in Tabriz, containing 40 mg zinc, one oral pill daily from 16 to 20 weeks until delivery

Category

Prevention

2

Description

Control group: tablet placebo made by pharmacy faculty in Tabriz, Containing 40 mg Micro Crystalline Cellulose , one oral pill daily from 16 to 20 weeks until delivery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Training - Medical center Akbar Abadi

Full name of responsible person

Shiva Azimi

Street address

Ferdose garden station, Molavi street, Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Training - Medical center Mahdie

Full name of responsible person

Shiva Azimi

Street address

Fedayeen Islam street, Shush square, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Shiva Azimi

Street address

Shaheed Sardar Barande Saifi square,
Eslamshahr, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

Street address

Research department, third floor, central construction
number 2, Tabriz University of Medical Sciences,
Golgashat Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Deputy of Tabriz 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

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Shiva Azimi

Position

Master of Sciences student in midwifery

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

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Position

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

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Person responsible for updating data

Contact

Name of organization / entity

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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