

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Clinical trial of the effects of garlic tablet in reduction of premature labor in women

Protocol summary

Summary

Objective: To assess Effect of garlic in reducing preterm labor in women Design: Randomized and placebo-controlled, double-blind, single-center. Method: Pregnant women randomly assigned to one of two groups garlic consumption and the use of progesterone suppository 400 mg or placebo and 400 mg progesterone suppository in other group. Informed consent will be taken of all participants. Inclusion criteria: Personal or family history of premature labor, abdominal surgery during pregnancy, high-risk jobs, a history of bleeding the first trimester, multiparity, uterine anomalies, uterine myoma, a history of second-trimester abortion, history cervical surgery, age less than 18 or more than 40, hemoglobin less than 10. Exclusion criteria: disease such as diabetes, hypertension, autoimmune diseases, major fetal anomaly, cerclage, drug allergies, along with placental abruption and preeclampsia Outcome: Determine of premature labor less than 37 weeks in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011824754N4**

Registration date: **2017-01-20, 1395/11/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-20, 1395/11/01

Registrant information

Name

Neda Hajiha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8163 3615

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2017-01-29, 1395/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effects of garlic tablet in reduction of premature labor in women

Public title

Clinical trial of the effects of garlic tablet in reduction of premature labor in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Personal or family history of premature labor, abdominal surgery during pregnancy, high-risk jobs, a history of bleeding the first trimester, multiparity, uterine anomalies, uterine myoma, a history of second-trimester abortion, history cervical surgery, age less than 18 or more than 40, hemoglobin less than 10. Exclusion criteria: disease such as diabetes, hypertension, autoimmune diseases, major fetal anomaly, cerclage,

drug allergies, along with placental abruption and preeclampsia

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **580**

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**

Ethic committee, Tehran University of Medical Sciences

Street address

Tehran

City

Tehran

Postal code**Approval date**

2016-05-10, 1395/02/21

Ethics committee reference number

IR.TUMS.REC.1395.2581

Health conditions studied**1****Description of health condition studied**

Premature Labor

ICD-10 code

060.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery

Primary outcomes**1****Description**

Delivery before 37 weeks of pregnancy

Timepoint

Weekly

Method of measurement

Count the number of weeks from the first day of the last menstrual period

Secondary outcomes

empty

Intervention groups**1****Description**

Therapeutic intervention with drug: garlic tablets (tablets coated 600 mg garlic) with suppository 400 mg of progesterone for 16 to 22 weeks

Category

Prevention

2**Description**

Therapeutic intervention with placebo: progesterone suppository 400 mg with pharmaceutical starch for 16 to 22 weeks

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mohebe Yas Hospital

Full name of responsible person**Street address**

North Villa St.

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Tehran University of Medical Science, Ghods street, Keshavarz Blvd., Tehran

City

Tehran

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, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Zeina Shaker Ardakani

Position

Assistant of Obstetrics and Gynecology

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Full Professor

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Tehran University of Medical Sciences

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Zeina Shaker Ardakani

Position

Assistant of Obstetrics and Gynecology

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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