

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The effect of garlic tablet on plasma nitric oxide levels and prevention of preeclampsia in healthy nulliparous women: A randomized controlled trial

Protocol summary

Summary

The purpose of this clinical trial, with two triple-blind parallel arms, is to determine the effect of garlic tablet on the plasma levels of nitric oxide and prevention of preeclampsia which will be tested on 400 pregnant women with gestational age of 20 weeks, nulliparous and without a history of hypertension who referred to Health centers in Rasht. Eligible people after obtaining written informed consent, with randomized block method, with four and six blocks and allocation ratio of 1:1 would be allocated in two groups. To conceal allocation and preservation of blinding of participants and people involved in sampling and data collection, tablets containing 400 mg of garlic powder (construction Dineh pharmaceutical company, containing of 1100 to 1400 micrograms allicin) and placebo quite similar to garlic tablet by a uninvolved person in the sampling and data collection will be placed in a sealed opaque envelope with consecutive numbers. Persons will intake prescription tablets daily (every 12 hours 1 tablet) for 16 weeks. The plasma nitric oxide levels 12 weeks after intervention and blood pressure measurements (to determine the frequency of preeclampsia incidence) in the specified visits as a primary consequences, the frequency of preterm delivery incidence, anthropometric indexes, the satisfaction level of received drug and side events as a secondary consequences will be assessed and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602163027N33**

Registration date: **2016-04-08, 1395/01/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-08, 1395/01/20

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of garlic tablet on plasma nitric oxide levels and prevention of preeclampsia in healthy nulliparous women: A randomized controlled trial

Public title

The effect of garlic tablet on plasma nitric oxide levels and prevention of preeclampsia in healthy nulliparous women: A randomized controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having ultrasound based on singleton pregnancy and baby health, 20 weeks pregnancy (according to gestational age in the early pregnancy ultrasound), pregnant women 18-35 years, failure to alcohol and tobacco, having at least read and write, having telephone number for follow-up Exclusion criteria: Systemic diseases such as diabetes mellitus, heart disease, kidney and... according to pregnant women statement, history of clotting disorders, history of hypertension disorder before pregnancy and during current pregnancy, body mass index equal to or greater than 30 kilograms per square meter, systolic blood pressure lower than 100 mmhg, history of allergy to garlic according to pregnant women statement, intake garlic more than 1 serving a day or more than 10 serving per week, participate in other similar studies.

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: **400**

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**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor Of Research, Number 2 Central Building, Tabriz University of Medical Sciences, Golgasht ave, Tabriz, Iran

City

Tabriz

Postal code

5165665931

Approval date

2016-02-01, 1394/11/12

Ethics committee reference number

TBZMED.REC.1394.1028

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

Supervision of normal first pregnancy for prevention of preeclampsia

ICD-10 code

Z34.0

ICD-10 code description

Supervision of normal first pregnancy

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

Plasma nitric oxide level

Timepoint

12 weeks after intervention

Method of measurement

Nitric oxide kit

2**Description**

The frequency of preeclampsia incidence

Timepoint

Before intervention, 6-10,11-14, 15-17 and 18-20 weeks after intervention

Method of measurement

The blood pressure according to millimeter of mercury using a mercury sphygmomanometer and random urine albumin using diagnostic strips for urine protein assay

Secondary outcomes**1****Description**

The frequency of side events incidence

Timepoint

8 and 16 weeks after intervention

Method of measurement

The side events check list

2**Description**

Neonatal anthropometric indexes

Timepoint

After the termination of pregnancy

Method of measurement

Growth monitoring card

3**Description**

The frequency of preterm delivery incidence
Timepoint
During 16 weeks after intervention
Method of measurement
The folder summary sheet in Health centers

4

Description
The patients satisfaction level of received drug
Timepoint
8 and 16 weeks after intervention
Method of measurement
The check list of satisfaction of received drug

Intervention groups

1

Description
Intervention group: Garlic tablet, 400 milligram, oral, every 12 hours 1 tablet for 16 weeks
Category
Prevention

2

Description
Control group: Placebo, oral, quite similar to garlic tablet, every 12 hours 1 tablet for 16 weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Center Number 8
Full name of responsible person
Darvishi, Farzaneh
Street address
No.43 In Front of the Faculty of Nursing and Midwifery, Student Park, Hamidian Ave, Rasht, Iran
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research of Tabriz University of Medical Sciences
Full name of responsible person
Dr Mirghafourvand
Street address
Faculty of Nursing and Midwifery, Shariati Ave, Tabriz, Iran
City

Tabriz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research 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
Faculty of Nursing and Midwifery
Full name of responsible person
Shafaie Sehhatie Fahimeh
Position
Master of Midwifery
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, Shariati Ave, Tabriz, Iran
City
Tabriz
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3475 2839
Email
sehhatief@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery
Full name of responsible person
Shafaie Sehhatie Fahimeh
Position
Master of Midwifery
Other areas of specialty/work
Street address
Faculty of Nursing and Midwifery, Shariati Ave, Tabriz,

Iran
City
Tabriz
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3475 2839
Email
sehhatief@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Faculty of nursing and midwifery
Full name of responsible person
Shafaie Sehhatie Fahimeh
Position
Master of Midwifery
Other areas of specialty/work
Street address
Faculty of nursing and midwifery, Shariati Ave, Tabriz,
Iran
City

Tabriz
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3475 2839
Email
sehhatief@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

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