# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 2026

## The effect of Ginseng on sexual dysfunction in menopausal women: a double blinded randomized control

## Protocol summary

**Study aim**

Determining the effect of Ginseng on sexual dysfunction in menopausal women: a randomized controlled trial

**Design**

Two-armed randomized controlled trial. Conduct: This study will be conducted on 62 postmenopausal women ages 45-60 years old referring to community health centers in Tabriz. Eligible individuals who has Female Sexual Function Index (FSFI) score less than 28 at the initial evaluation will be included in the study. After obtaining written informed consent, they will complete questionnaires of quality of life, menopausal symptoms and demographic characteristics. Next, they will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4 and 6 and the allocation ratio of 1:1.

**Settings and conduct**

This study will be conducted on 62 postmenopausal women ages 45-60 years old referring to community health centers in Tabriz. The intervention group will receive Ginseng capsules and the control group will receive placebo capsules. Both groups will take drug or placebo twice a day for four weeks

**Participants/Inclusion and exclusion criteria**

inclusion criteria: Married women; Women aged between 45 and 60 years; Last menstruation period between 12 months and 10 years; Female Sexual Function Index (FSFI) score less than 28 at the initial evaluation. Exclusion criteria: Coronary artery disease or other heart problems such as significant arrhythmia; Uncontrolled diabetes mellitus; Uncontrolled hypertension; Blood pressure lower than 90/50 mmHg; A history of radical hysterectomy; Anatomical deformity of external genitalia; A history of cerebrovascular disease or central nervous system disease; A history of spinal cord injury or related surgery; Having liver disorder; Kidney dysfunction; Intake of medicine such as amlodipine, valerian, and lorazepam (which are known to have interactions with ginseng); History of hormonal treatment for sexual dysfunction during the past two weeks; A history of chemotherapy or pelvic radiation treatment; Sexual dysfunction which was caused by mental disease; Present use of Phytoestrogens and other complementary or herbal medicine; Post coital bleeding or spotting

**Intervention groups**

The intervention group will receive Ginseng capsules and the control group will receive placebo capsules.

**Main outcome variables**

The main outcome variables include sexual function that will be assessed by Female Sexual Function Index.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20120718010324N32**
Registration date: **2017-12-31, 1396/10/10**
Registration timing: **retrospective**

Last update: **2017-12-31, 1396/10/10**
Update count: **0**

**Registration date**

2017-12-31, 1396/10/10

**Registrant information**

**Name**
Mojgan Mirghafourvand
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Tabriz University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Tabriz University of Medical Sciences

**Expected recruitment start date**
2016-12-21, 1395/10/01
**Expected recruitment end date**
2017-04-20, 1396/01/31
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of Ginseng on sexual dysfunction in menopausal women: a double blinded randomized control

**Public title**
The effect of Ginseng on sexual function in menopausal women
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Married women Women ages between 45 and 60 years Last menstruation period between 12 months and 10 years Female Sexual Function Index (FSFI) score less than 28 at the initial evaluation Having sex at least two times per month. incidence of menopause naturally not following surgery (hysterectomy)
**Exclusion criteria:**
Coronary artery disease or other heart problems such as significant arrhythmia Uncontrolled diabetes mellitus Uncontrolled hypertension Blood pressure lower than 90/50 mmHg A history of radical hysterectomy Anatomical deformity of external genitalia A history of cerebrovascular disease or central nervous system disease A history of spinal cord injury or related surgery Having liver disorder Kidney dysfunction Intake of medicine such as amlodipine, valerian, and lorazepam (which are known to have interactions with ginseng) History of hormonal treatment for sexual dysfunction during the past two weeks A history of chemotherapy or pelvic radiation treatment Sexual dysfunction which was caused by mental disease Present use of Phytoestrogens and other complementary or herbal medicine Post coital bleeding or spotting
**Age**
From **45 years** old to **60 years** old
**Gender**
Female

**Phase**
1-2
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **62**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4 and 6 and the allocation ratio of 1:1. A person not involved in the sampling will generate allocation sequence.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The participants and investigator will be blind completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in research.
**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
**City**
Tabriz
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East Azarbaijan
**Postal code**
.....
**Approval date**
2017-11-06, 1396/08/15
**Ethics committee reference number**
IR.TBZMED.REC.1396.715

## Health conditions studied

### 1

**Description of health condition studied**
Sexual Dysfunction
**ICD-10 code**
F52
**ICD-10 code description**
Sexual dysfunction, not caused by organic disorder or disease

## Primary outcomes

### 1

**Description**
sexual function
**Timepoint**
before and 4 weeks after intervention
**Method of measurement**
Female Sexual Function Index Questionnaire

## Secondary outcomes

### 1

**Description**
Quality of Life
**Timepoint**
Before and 4 weeks after intervention
**Method of measurement**
Menopause Quality Of Life Questionnaire ( MENQOL)

### 2

**Description**
Menopausal Symptoms
**Timepoint**
Before and 4 weeks after intervention
**Method of measurement**
Greene scale

## Intervention groups

### 1

**Description**
The intervention group will receive Ginseng capsule twice daily for 4 weeks.
**Category**
Treatment - Drugs

### 2

**Description**
The control group will receive placebo capsule twice daily for 4 weeks
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Community health centers of Tabriz
**Full name of responsible person**
Zahra Ghorbani
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## Sponsors / Funding sources

### 1

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**Web page address**
http://researchvice.tbzmed.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Tabriz University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

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Zahra Ghorbani
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There no more information.
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
The results of clinical study will be published as article.
**When the data will become available and for how long**
Immediately after publishing the results.
**To whom data/document is available**
All researchers
**Under which criteria data/document could be used**
Scientific using with citation to article.
**From where data/document is obtainable**
Email: mirghafourvandm@tbzmed.ac.ir
**What processes are involved for a request to access data/document**
Maximum one week after the communication by email.
**Comments**