

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

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Province

East Azarbaijan

Postal code

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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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Tabriz's Community health centers

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

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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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Ghorbani

Position

Msc Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Position

Associate Professor/ PhD of Reproductive Health

Latest degree

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Other areas of specialty/work

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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**Person responsible for updating data**