

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of ginseng herbal medicine on the sexual Function of patients with diabetes

#### Protocol summary

##### Study aim

Determining the scores of women's orgasmic performance, premature ejaculation performance, sexual desire/arousal in women, erectile dysfunction, delayed ejaculation and determining the levels of LDLc, HDL, testosterone, prolactin and HBA1C in patients with diabetes in the intervention and control groups before and after the intervention.

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients. A sealed envelope was used for randomization.

##### Settings and conduct

This study will be conducted in the field of impotence treatment in Yasouj center. 100-200 mg of ginseng capsules will be investigated on impotence with diabetes. The study was double-blind, where the researchers were blinded to the grouping. The participants, fully aware of the type of intervention but blinded to the grouping, were randomly divided into two groups receiving ginseng and placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 30 to 55 years old suffering from diabetes Be sexually active Exit criteria: physical disability Treatment for any sexual dysfunction in the past 6 months Prescribing Coumadin (warfarin), heparin, daltaparin, enoxaparin or any other anticoagulant treatment Prescribing levodopa for Parkinson's disease or calcipotriene for psoriasis Diagnosing high blood pressure and prescribing antihypertensive drugs Severe renal or hepatic failure Anatomical anomalies of the reproductive system Prostate Cancer Genital surgery Chronic abuse Allergy to ginseng

##### Intervention groups

1- The intervention group receiving ginseng herbal medicine 2- Control group receiving placebo

##### Main outcome variables

Female orgasmic performance, premature ejaculation performance, sexual desire/arousal in women, erectile

dysfunction, delayed ejaculation and levels of LDLc, HDL, testosterone and prolactin and HBA1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231129060218N2**

Registration date: **2024-01-21, 1402/11/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-01-21, 1402/11/01**

Update count: **0**

##### Registration date

2024-01-21, 1402/11/01

##### Registrant information

##### Name

Zahra Rahami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3333 7251

##### Email address

zahra.rahami@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2024-12-21, 1403/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of ginseng herbal medicine on the sexual Function of patients with diabetes

**Public title**

Ginseng herbal medicine on the sexual Function

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Heterosexual men and women aged 35 to 55 Who have been sexually active for at least 6 months Who will be sexually active in the next 8 weeks Who will obtain approval score score on the relevant sexual dysfunction questionnaire

**Exclusion criteria:**

Any physical disability that can limit sexual function Receiving any treatment for any sexual disorder in the past 6 months Prescribing Coumadin, warfarin, heparin, dalteparin, enoxaparin, or any other anticoagulant therapy Prescribing levodopa for Parkinson's disease or calciputerin for psoriasis Diagnosing high blood pressure and prescribing antihypertensive drugs Severe renal or hepatic failure Anatomical anomalies of the reproductive system Uncontrolled diabetes mellitus History of spinal cord injury Uncontrolled sexual secondary mental disorders Diagnosed prostate cancer or benign hypertrophy History of genital surgery History of chronic alcohol or drug abuse Suspected or diagnosed allergy to ginseng Participation in any other clinical trial in the past 30 days

**Age**

From **35 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization process in the present study will involve using sealed envelopes. Initially, a random sequence of numbers will be generated. Subsequently, a corresponding number of envelopes lined with aluminum foil will be prepared based on the research sample size. Each of the created random sequences will be transcribed onto a card, with the cards then being placed inside the envelopes in sequential order. Finally, the envelopes will be sealed and placed in a box according to their order. Upon participant registration, an envelope will be opened based on the entry sequence of eligible

participants, revealing the assigned group for that participant.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Initially, all patients received a thorough and comprehensive explanation of the study's objectives. Clear and detailed explanations about the intervention type and the effects of ginseng were provided to all patients. Subsequently, as patients will be allocated to either the control or intervention groups based on a specific code, they will be kept unaware of their assignment to the intervention or control group, in contrast to receiving a placebo or ginseng herbal medicine. Announcements will be made. Caregivers at the patient's bedside will be informed by the investigators, and both the data collector and data analyst will be kept unaware of the grouping.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of yasuj university of medical science

**Street address**

Saheli street\_ yasuj university of medical science

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591846667

**Approval date**

2023-11-01, 1402/08/10

**Ethics committee reference number**

IR.YUMS.REC.1402.120

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

Sexual function of in diabetic patients

**ICD-10 code**

F52

**ICD-10 code description**

Sexual dysfunction not due to a substance or known physiological condition

## Primary outcomes

### 1

#### Description

Women's orgasmic performance scores

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

Female Sexual Function Index (FSFI)

### 2

#### Description

Premature ejaculation performance of patients

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

The international index of erectile function (IIEF)

### 3

#### Description

Sexual desire/arousal

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

The international index of erectile function (IIEF) and Female Sexual Function Index (FSFI)

### 4

#### Description

Erectile dysfunction scores of patients

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

The international index of erectile function (IIEF) and Female Sexual Function Index (FSFI)

### 5

#### Description

Delayed ejaculation scores

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

The international index of erectile function (IIEF) and Female Sexual Function Index (FSFI)

### 6

#### Description

Determination of LDL, HDL, testosterone, prolactin and HBA1C levels

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

Calibrated laboratory instruments

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: recipient of ginseng capsules, containing 100 mg of ginseng, prepared by Dana company, two capsules per day, for 8 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo capsule recipient, two capsules per day, for 8 weeks, the placebo will be prepared by the researchers using the empty capsule, size number 1, and wheat flour.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Sajjad Hospital

##### Full name of responsible person

Zahra Rahami

##### Street address

Yasouj, Imam Hossein Square

##### City

Yasouj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591846667

##### Phone

+98 74 3322 2291

##### Email

zahra.rahami@yums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Seyed Amin Hossaini Motlagh

##### Street address

Yasouj, Shahid Motahari Blvd., Yasouj University of Medical Sciences, Research Assistant

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

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##### Phone

+98 74 3334 6079

**Email**

aminhomo@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Zahra Rahami

**Position**

Internist

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**Latest degree**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to

make this available