Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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

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Iran (Islamic Republic of)

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+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
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Yasouj, Imam Hossein Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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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

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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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