Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Ginseng and placebo on sexual performance status in men and women treated with methadone

Protocol summary

Summary

This study will be done to compare the impact of Ginseng and placebo on sexual performance status in men and women treated with methadone. The present research is a double blind clinical trial. The study sample population is consist of all men and women drug addicts referring to Methadone Maintenance Treatment Centers in Kermanshah, which 70 of them will be selected by census method, and will be categorized into control and experiment. The subjects of both groups will be matched in terms of age and Sex, and the FSFI sexual dysfunction questionnaire for women and international index of erectile dysfunction (IIEF) will be distributed among them. In the experimental group, the participants will receive daily four capsules of Ginseng, while the control group will receive four placebo capsules daily. The questionnaire will be re-distributed among both groups at the first and at the end of the study (4 weeks after the start of the study), and the sexual function in men and women will be measured. Inclusion criteria: patients undergoing methadone treatment; married; age between 18-50 years; lack of sexual problems before treatment with methadone. Exclusion criteria: Under age of 18, drugs that positive and negative affect on sexual performance, recent use any other drugs or alcohol, spinal cord injury, radical prostatectomy, singular, the existence of recent mental disorder, recent communication disorder with wife, allergy to Ginseng.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062523705N5**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name
Mostafa Alikhani
Name of organization / entity
Kermanshah University of Medical Sciences - Substance Abuse Prevention Research Center
Country
Iran (Islamic Republic of)
Phone
+98 838264513
Email address
mo.alikhani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Ginseng and placebo on sexual performance status in men and women treated with methadone

Public title

Effect of Ginseng on sexual performance status in men and women

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing methadone treatment; married; age between 18-50 years; lack of sexual problems before treatment with methadone. Exclusion criteria: Under age of 18, drugs that positive and negative affect on sexual performance, recent use any other drugs or alcohol, spinal cord injury, radical prostatectomy, singular, the existence of recent mental disorder, recent communication disorder with wife, allergy to Ginseng.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2016-06-08, 1395/03/19
Ethics committee reference number
IR.KUMS.REC.1395.178

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 dysfunction
Timepoint
The beginning of the study (baseline) and end of the study (week four)
Method of measurement
Based on sexual function questionnaire (IIEF) for men and sexual function questionnaire (FSFI) for women

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group, the participants will receive four capsules of Ginseng daily ,then the questionnaire will be re-distributed at the baseline and at the end of the study (4 weeks after the start of the study), and sexual function will be measured
Category
Treatment - Drugs

2

Description
In the control group participant will receive four placebo capsules daily. then questionnaire will be redistributed at baseline and at the end of the study (4 weeks after the start of the study), and sexual function will be measured.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Methadone Maintenance Treatment Centers
Full name of responsible person
Street address
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Vahid Farnia
Position
Psychiatrist
Other areas of specialty/work
Street address
Farabi Hospital, Isar square
City
Kermanshah
Postal code
Phone
+98 83 3826 4513
Fax
Email
vfarnia@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Alireza Ebrahimi
Position
Psychiatrist
Other areas of specialty/work
Street address
Farabi Hospital, Isar square
City
Kermanshah
Postal code
Phone
+98 83 3826 4513
Fax
Email
alirezaebrahimi1344@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Vahid Farnia
Position
Psychiatrist
Other areas of specialty/work
Street address
Farabi Hospital, Isar square
City
Kermanshah
Postal code
Phone
+98 83 3826 4513
Fax
Email
Web page address

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