Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Rose essence on improving sexual dysfunction and increase happiness in women treated with methadone

Protocol summary

Summary

The current research aims to examine the effect of rose essence on the improvement of sexual dysfunction caused by methadone administration and increase of happiness in the women treated with methadone. The research is a double blind clinical trial. The research's statistical population is composed of all the women drug addicts referring to the addiction treatment center and Kermanshah Farabi Hospital, which 60 of them will be selected by an accessible method, and categorized into two groups of the control and experiment. The subjects of the experimental and control groups will be matched in terms of age, and the FSFI sexual dysfunction and happiness questionnaires will be distributed among them. In the experimental group, the participants will receive daily a capsule of rose essence a day, while the control group will receive a placebo capsule daily. The questionnaire will be re-distributed among both groups at the first, 4 weeks later, and at the end of the study (8 weeks after the start of the study), and the amount of happiness and amount of sexual function and happiness will be measured among them. In addition, at the beginning and end of the study, the blood sample will be sent to the laboratory in order to determine the level of the hormones, and the level of the hormones will be measured. Inclusion criteria: patients undergoing methadone treatment; minimum elementary education; married; age between 20-48 years; lack of sexual problems before treatment with methadone. Exclusion criteria: allergy to products made from rose essence; history of any endocrine disease such as elevated prolactine, thyroid disorders, and change in sexual activity because of pregnancy of wife, remarriage, and divorce.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091523705N2**
Registration date: **2015-10-30, 1394/08/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-30, 1394/08/08

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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Rose essence on improving sexual dysfunction

and increase happiness in women treated with methadone

Public title
Effect of Rose Essence on women's sexual dysfunction and happiness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing methadone treatment; minimum elementary education; married; age between 20-48 years; lack of sexual problems before treatment with methadone. Exclusion criteria: allergy to products made from rose essence; history of any endocrine disease such as elevated prolactine, thyroid disorders, and change in sexual activity because of pregnancy of wife, remarriage, and divorce.
Age
From **20 years** old to **48 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
2015-08-18, 1394/05/27
Ethics committee reference number
kums.rec.1394.57

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), week four and end of the study (week eight)
Method of measurement
Based on sexual function questionnaire (FSFI)

2

Description
happiness
Timepoint
The beginning of the study (baseline), week four and end of the study (week eight)
Method of measurement
Based on happiness questionnaire

3

Description
level of the hormone
Timepoint
Beginning and end of the study (week eight)
Method of measurement
By Blood Test

Secondary outcomes

empty

Intervention groups

1

Description
The control group will receive a placebo capsule daily.
Category
Placebo

2

Description
In the experimental group, the participants will receive daily one capsule of rose essence
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi Hospital-Addiction recovery center of Kermanshah city

Full name of responsible person
Mostafa Alikhani

Street address
Farabi hospital,Isar Blvd

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

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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