

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Email address

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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 prolactin, 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

**Street address**

Isar square, Farabi Hospital

**City**

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**Phone**

0083309125188875

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vfarnia@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

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Dr. Faezh Tatari

**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Vfarnia@yahoo.com

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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*