

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of Rose Essence and placebo in improving sexual disorders and increase of happiness in men treated with methadone

#### Protocol summary

##### Summary

This study will be done to compare the impact of Rose Essence and placebo in improving sexual dysfunction , caused by methadone and increase of happiness in men treated with methadone . The research is a double blind clinical trial. The study sample population is consist of all male drug addicts referring to the addiction treatment center of Farabi Hospital in Kermanshah, which 60 of them will be selected by convenience method, and will be categorized into control and experiment. The subjects of both groups will be matched in terms of age, and the erectile function and happiness questionnaires will be distributed among them. In the experimental group, the participants will receive a capsule of rose essence daily , 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 happiness and sexual function will be measured . 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.. Inclusion criteria: patients under methadone treatment; at least elementary education;be married; age between 20-48 years; have not sexual problems before treatment with methadone; no history of any glands disease, such as elevated prolactin and thyroid disorder. Exclusion criteria: allergy to products made from rose essence; changes in sexual activity because of (wife pregnancy, remarried, divorce).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015091523705N1**

Registration date: **2015-12-15, 1394/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-15, 1394/09/24

##### 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

2015-09-18, 1394/06/27

##### Expected recruitment end date

2015-11-18, 1394/08/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Rose Essence and placebo in improving  
sexual disorders and increase of happiness in men  
treated with methadone

##### Public title

Effect of Rose Essence on sexual dysfunction and

happiness

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients under methadone treatment; elementary education or higher; married; age between 20-48 years; have not sexual problems before treatment with methadone; no history of any glands disease, such as elevated prolactin and thyroid disorder. Exclusion criteria: allergy to products made from rose essence; changes in sexual activity because of (wife pregnancy, remarried, divorce).

## Age

From **20 years** old to **48 years** old

## Gender

Male

## 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

Randomization will be done by coin toss and patients will be assigned to either control or experimental group. In both groups, patients and the facilitator do not know which group will receive Rose Essence and which group will receive placebo. So, it is a double-blind clinical trial.

## 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.1394.58

## 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 (IIEF)

### 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(OHI)

### 3

#### Description

level of the Thyroid hormone

#### Timepoint

Beginning and end of the study (week eight)

#### Method of measurement

By experimental Kit

### 4

#### Description

Sexual hormones level

#### Timepoint

The baseline and end of the study(Eighth week)

#### Method of measurement

By experimental Kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the experimental group, the participants will receive a

capsule of rose essence daily ,then the questionnaire will be re-distributed at the baseline, 4 weeks later, and at the end of the study (8 weeks after the start of the study), and the happiness and sexual function will be measured. 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 T4, T3, Thyroid, and Testosterone, and the level of the hormones will be measured.

**Category**

Treatment - Drugs

**2****Description**

In the control group participant will receive a placebo capsule daily. then questionnaire will be redistributed at baseline,4 weeks later, and at the end of the study (8 weeks after the start of the study), and the happiness and sexual function will be measured. 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 T4, T3, Thyroid, and Testosterone, and the level of the hormones will be measured.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Farabi Hospital-Addiction recovery center

**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**

Isar square, Farabi Hospital

**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.Jalal Shakeri

**Position**

Psychiatrist

**Other areas of specialty/work****Street address**

Isar square, Farabi Hospital

**City**

Kermanshah

**Postal code****Phone**

+98 83 3827 6683

**Fax****Email**

Jshakeri@kums.ac.ir

**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**

Isar square, Farabi Hospital

**City**

Kermanshah

**Postal code**

**Phone**

008338264513

**Fax**

**Email**

Vfarnia@yahoo.com

**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*