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
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Name of organization / entity
Kermanshah University of Medical Sciences - Substance Abuse Prevention Research Center
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-09-18, 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

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Isar square, Farabi Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Jalal Shakeri

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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