

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The efficacy of use and without use of Rosa damascene extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in men with Major Depressive Disorder

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy of Rosa damascenes extracts in the treatment of sexual dysfunction induced by serotonin reuptake inhibitors in men with major depressive disorders. This is a triple-blind clinical trial. 60 married men referred to Kermanshah Farabi Hospital were selected and randomly divided into two groups. The intervention group received 3 cc Rosa damascenes drop daily for 8 weeks which was equivalent to 17 mg citronellol. The control group received 3 cc distilled water (placebo) daily. Then at the beginning of the study, fourth and eighth week of the study, libido and sexual level, erection times, hardness and stiff of erection, hardness of flow out of semen, the problem of amount and flow out of semen, lack of libido, the problem of become erect and keeping it, and sexual satisfaction were examined. Inclusion criteria: Patients with major depressive disorders; and those who had been treated with a fixed dose of serotonin reuptake inhibitors for at least eight weeks; those who haven't sexual disorder before begin the treatment and they affected sexual disorder with use of this medicines. Exclusion criteria: presence of sexual dysfunction before taking serotonin reuptake inhibitors; presence of any systemic or psychiatric disorders, Thyroid disease and hyperprolactinemia or taking any medication which affects sexual activity; any history of drug or alcohol use during 6 recent months; those who have recently had significant changes in sexual activity due to their wife pregnancy, remarriage and divorce.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100814333N10**
Registration date: **2013-10-22, 1392/07/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-22, 1392/07/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of use and without use of Rosa damascene extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in men with Major

Depressive Disorder

Public title

The efficacy of Rosa damascene extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in men with Major Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major depressive disorders according to DSM IV; and those who had been treated with a fixed dose of serotonin reuptake inhibitors for at least eight weeks; those who haven't sexual disorder before begin the treatment and they affected sexual disorder with use of this medicines such as decrease of libido, erection disorder, delay of orgasm or dis ability to become orgasm Exclusion criteria: presence of sexual dysfunction before taking serotonin reuptake inhibitors; presence of any systemic or psychiatric disorders, Thyroid disease and hyperprolactinemia or taking any medication which affects sexual activity; any history of drug or alcohol use during 6 recent months; those who have recently had significant changes in sexual activity due to their wife pregnancy, remarriage and divorce

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

2010-09-23, 1389/07/01

Ethics committee reference number

11884/7/420/پ

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

Days libido

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

2

Description

libido

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

3

Description

Erection times

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

4

Description

Erection stiff

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

5

Description

Erection hardness

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

6

Description

Hardness of flow out of semen

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

7

Description

The problem of semen Amount

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

8

Description

The problem of lack of semen

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

9

Description

Sexual Satisfaction

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

10

Description

The problem of ability to become erect and keeping it

Timepoint

At the beginning, 4th and 8th the week of study

Method of measurement

Asking the patient

11

Description

Serotonin reuptake inhibitors

Timepoint

At the beginning, 4th and 8th the study week of

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group received 3 cc Rosa damascenes drop daily for 8 weeks which was equivalent to 17 mg citronellol

Category

Treatment - Drugs

2

Description

The control group received 3cc distilled water (placebo) daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Dr. Mehdi Shirzadifar

Street address

first of Dolatabad Boulevard, Eisar Squqre

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

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

Person responsible for scientific 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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first of Dolatabad Boulevard, Eisar Squqre
City
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Postal code
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+98 83 1826 0700
Fax
Email
vfarnia@kums.ac.ir
Web page address

Person responsible for updating data

Contact

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