Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

The efficacy of use and without use of Rosa damascene extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptale 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

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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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 Reuptale Inhibitors in men with Major

Depressive Disorder

Public title
The efficacy of Rosa damascene extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptale 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 Boulvard,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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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