

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

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

Protocol summary

Summary

The purpose of this study was to evaluate the efficacy of Rosa damascenes extracts in the treatment of sexual dysfunction induced by serotonin reuptake inhibitors in women with major depressive disorders. This is a triple-blind clinical trial. 50 married women referred to Kermanshah Farabi Hospital were selected and randomly divided into two equal intervention and control groups. The intervention group received 3cc Rosa damascenes drop daily for 8 weeks which was equivalent to 17mg citronellol. The control group received 3cc distilled water (placebo) daily. Then at the beginning of the study, four and eight weeks of the study, libido, sexual arousal levels, orgasmic disorders, sexual pain disorders and sexual satisfaction were examined. Inclusion criteria: Patients with major depressive disorder according to DSM IV; and those who had been treated with a fixed dose of serotonin reuptake inhibitors for at least eight weeks. 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 pregnancy, remarriage and divorce.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100114333N9**

Registration date: **2013-10-18, 1392/07/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-18, 1392/07/26

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

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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 damascenes extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in women with Major Depressive Disorder

Public title

The efficacy of Rosa damascenes extract in treatment of sexual dysfunction induced by Selective Serotonin

Reuptake Inhibitors in women with Major Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major depressive disorders according to DSM IV; those who had been treated with a fixed dose of serotonin reuptake inhibitors for at least eight weeks. 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 pregnancy, remarriage and divorce

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

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

Vice Chancellor for Research Affairs, 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

2013-06-25, 1392/04/04

Ethics committee reference number

12495/7/420/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

libido

Timepoint

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

Method of measurement

Asking the patient

2

Description

Levels of sexual arousal

Timepoint

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

Method of measurement

Asking the patient

3

Description

Orgasmic disorders

Timepoint

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

Method of measurement

Asking the patient

4

Description

Sexual pain disorders

Timepoint

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

Method of measurement

Asking the patient

5

Description

Sexual Satisfaction

Timepoint

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

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group received 3cc Rosa damascenes dropdaily for 8 weeks which was equivalent to17mg 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. Sara hojatitabar

Street address

First of Dolatabad Boulevard,Eisar Square

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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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