Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The efficacy of use and without use of Rosa damascenes extract in treatment of sexual dysfunction induced by Selective Serotonin Reuptale 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 reup take 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 in to two equal intervention and control groups.The intervention group received 3cc Rosa damascenes drop daily for 8 weeks which was equivalent to17mg citronellol.The control group received 3cc distilled water (placebo)daily.Then at the beginning of the study, four and eight week of the study, libido,sexual arousallevels, orgasmic disorders, sexual pain disorders and sexual satisfaction were examined.Inclusion criteria: Patients with major depressive disorder saccording to DSM IV; and those who had been treated with a fixed dose of serotonin reup take in hibitors for at least eight weeks. Exclusion criteria: presence of sexual dysfunction before taking serotonin reup take 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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 Reuptale Inhibitors in women with Major Depressive Disorder

Public title

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

Reuptale Inhibitors in women with Major Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with major depressive disorders according toDSM IV; those who had been treated with a fixed dose of serotonin reup take in hibitors for at least eight weeks. Exclusion criteria: presence of sexual dysfunction before taking serotonin reup take inhibitors; presence of anysystemic or psychiatric disorders , Thyroid disease and hyperprolactinemia or taking any medication which affects sexual activity; anyhistory 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 Boulvard,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
Street address
First of Dolatabad Boulvard,Eisar Square
City
Kermanshah
Postal code
Phone
+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