

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

froughi@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 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

##### Street address

First of Dolatabad Boulevard,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*