

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

Investigating the effect of royal jelly on Post-SSRI Sexual Dysfunction (PSSD) due to the use of selective serotonin reuptake inhibitors

Protocol summary

Study aim

1. Determination of response to treatment in the Royal gel and Placebo recipient group at 2, 4 and 8 weeks after treatment based on a questionnaire 2. Comparison of treatment response in the royal recipient group with placebo group at 2, 4 and 8 weeks after treatment based on age, sex, education questionnaire

Design

The study, a double-blind randomized controlled clinical trial, was performed on 60 patients who were taking antidepressants with selective serotonin receptor inhibitors who had sexual problems with these drugs. The sampling method will be available (easy) and the subjects will be divided into two intervention and control groups using random permutation block (4 blocks). The intervention group will receive royal jelly capsules (1000 mg) once daily and the control group will receive placebo at Mashhad School of Pharmacy once daily for eight weeks.

Settings and conduct

60 patients of Sabzevar medical university's psychiatry clinic who had sexual dysfunction due to SSRI treatment, will be divided into two intervention and control groups using random permutation block (4 blocks) and will be given whether Royal gel or Placebo.

Participants/Inclusion and exclusion criteria

Entry criteria: 1. Patients with any mental disorder who require SSRI medication. 2. Patients who had sexual problems with SSRI medication. Exclusion criteria: 1. Patients who do not take SSRI. 2. Patients who did not develop drug-induced sexual problems. 3. Patients who have had a history of sexual problems before taking the drug. 4. Patients who do take SSRIs regularly.

Intervention groups

one capsule of Royal gel or Placebo, once a day for 8 weeks

Main outcome variables

SSRI Libido Royal gel

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191207045632N1**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

Registration date

2021-07-04, 1400/04/13

Registrant information

Name

Fateme Shokoohy

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3334 9579

Email address

mahdiand@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of royal jelly on Post-SSRI Sexual Dysfunction (PSSD) due to the use of selective serotonin reuptake inhibitors

Public title

Investigating the effect of royal jelly on Sexual Dysfunction due to the use of selective serotonin reuptake inhibitors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with any psychological disease that need SSRI patients with sexual dysfunction after using SSRI patients aged between 20 to 45

Exclusion criteria:

patients who do not use SSRI regularly patients who had sexual dysfunction history before using SSRI

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced (permuted) block randomization in this study people will be divided in 2 groups using block permutation. in this method A stands for who receives treatment and B stands for who's in control group. Considering the quadruple block, code 0 would be for AABB permutation, code 1 for ABAB, code 2 for ABBA, code 3 for BAAB, code 4 for BBAA and code 5 for BABA. then using Random numbers table one starting point will be chosen randomly. considering table's numbers layout, every number will be given it's own permutation for example if three random numbers be 2,0,1 treatment receiving layout in first 12 persons would be ABBAABBABAB. one of envelopes will be chosen randomly when the patient comes and based on the given words the patient will be in treatment or control group. thus at last every 60 person's designation in 2 groups will be done using choosing numbers from table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blinded clinical trial in which each person in the study will be assigned codes "A" and "B" that only researcher knows about the groups and the participants and the physician are unaware of the groups. the drug and the placebo have exact shape, cover, color and weight and only researcher knows which

one of them each patient is taking.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Science building, Tohid shahr Blvd, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2019-04-27, 1398/02/07

Ethics committee reference number

IR.MEDSAB.REC.1398.004

Health conditions studied

1

Description of health condition studied

post SSRI sexual dysfunction

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

sexual function

Timepoint

at the beginning of the study (before intervention), week 2, week 4, week 6 and week 8

Method of measurement

Arizona sexual experience scale (ASEX) and the changes in sexual functioning questionnaire (CSFQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Royal gel capsules which is made from freezing and grinding the Royal gel (queen bee's discharges) in Sabzevar university of medical science's lab will be given once a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: placebo consist of farina with the exact same color, weight and cover to intervention group's drug will be prescribed for 8 weeks and one pill a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar special clinic

Full name of responsible person

Reza Foroozan

Street address

next to Vaseii hospital, Sabzevar

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9617699117

Phone

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parastoo.shokuhi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshte Qorat

Street address

Research department, Sabzevar University of Medical Science building, Nuclear Martyrs Blvd, Sabzevar

City

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9617913114

Phone

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Email

vc.Research@medsab.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Shokoohy

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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No.131, 11th taleqani, sabzevar town

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Davood Mahdian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

information about level of sexual dysfunction during different time of research and response to drug

When the data will become available and for how long

6 month after publishment

To whom data/document is available

university research departments with related subjects and Pharmaceutical Companies

Under which criteria data/document could be used

in case of requirement for information to produce drug or develop the reasearch

From where data/document is obtainable

Fateme Shokoohy parastoo.shokuhi@yahoo.com
Dr.Davood Mahdian mahdiand64@gmail.com

What processes are involved for a request to access data/document

mailing the given contacts and sending required information

Comments

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fateme Shokoohy

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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