Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

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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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 ABBAAABBABAB. 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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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
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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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Person responsible for updating data

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medical student

Latest degree
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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