Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the efficacy of Tribulus Terrestris and Lepidium Meyeni extracts on improvement of sexual interest in females

Protocol summary

Study aim
Evaluation of the efficacy of Tribulus Terrestris and lepidium Meyeni extracts on improvement of sexual interest in females

Design
Clinical trial with control and parallel groups, randomized and double blind

Settings and conduct
This clinical double blind trial is conducted on 60 female patients with reduced sexual interest referring to Ebne Sina and Imam Reza Hospitals in Mashhad who are randomly assigned to three groups through simple randomization where the participants and outcome assessors are unaware of the grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Married women between 18 to 50 years old with lack of sexual interest based on DSM5; Normal pelvic examination; Normal breast examination in the past 2 month; no pregnancy and breastfeeding or not having menstruation for more than 2 months.
Exclusion criteria : Hormonal or anatomical diseases which prevent orgasm; History of cancer or psychological disorders which are under treatment; Husband's sexual problem; No active plan for divorce

Intervention groups
Control group: In this group, patients receive one capsule of placebo drug one hour after one of the meals daily for one month. Intervention group 1: In this group, patients receive one capsule of Tribulus Terrestris extract (produced in the faculty of pharmacy) one hour after one of the meals daily for one month. Intervention group 2: In this group, patients receive one capsule of Lepidium Meyenii extract (produced in the faculty of pharmacy) one hour one of the meals daily for one month.

Main outcome variables
rate of sexual interest

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101130005280N33**
Registration date: **2020-06-03, 1399/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-03, 1399/03/14**
Update count: **0**

Registration date
2020-06-03, 1399/03/14

Registrant information

Name
Raheleh Nejati

Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

Phone
+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-05, 1399/02/16

Expected recruitment end date
2020-11-06, 1399/08/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of Tribulus Terrestris and Lepidium Meyeni extracts on improvement of sexual interest in females

Public title
The efficacy of the extracts of Tribulus Terrestris and Lepidium Meyeni on improvement of sexual interest in females

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Married women between 18 to 50 years old with lack of sexual interest based on DSM5 (who has satisfactory relationship with her husband and live with him at least 15 days in a month and is also sexually active) Normal pelvic examination Normal breast examination in the past 2 month no pregnancy and breastfeeding not having menstruation for more than two months

Exclusion criteria:
Hormonal or anatomical diseases which prevent orgasm such as diabetes, cerebrovascular diseases, liver-kidney-heart problems, hypothyroidism History of cancer or psychological disorders which are under treatment such as breast and pelvic cancer or depression, anxiety and psychosis husband's sexual problem no active plan for divorce

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with table of random numbers available at ''www.randomization.com'' website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one patient and places her in one of the three groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants are not aware of the type of treatment and the intervention. Also, outcome assessors are unaware of the the grouping. Patients in the control group receive placebo drug.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-11-27, 1397/09/06

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.326

Health conditions studied

1

Description of health condition studied
sexual interest

ICD-10 code
F52.22

ICD-10 code description
Female sexual arousal disorder

Primary outcomes

1

Description
Rate of sexual interest

Timepoint
Before and at the end of the one -month treatment

Method of measurement
Administration of Arizona Sexual Experience Scale (ASEX)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, patients receive one capsule of Tribulus Terrestris extract (produced in the faculty of pharmacy) one hour after one of the meals daily for one month.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, patients receive one capsule of Lepidium Meyenii extract (produced in the faculty of pharmacy) one hour one of the meals daily for one month.
Category
Treatment - Drugs

3

Description
Control group: In this group, patients receive one capsule of placebo drug one hour one of the meals daily for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad University of Medical Sciences
Full name of responsible person
Mahdie Ghanbari
Street address
Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave
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9137913316
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ghanbarim951@mums.ac.ir

2

Recruitment center
Name of recruitment center
Ebnesina hospital
Full name of responsible person
Mahdie Ghanbari
Street address
Ebnesina hospital, Horre Ameli Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Ali Manteghi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after patients are made unidentifiable
When the data will become available and for how long
Data can be accessible 6 months after results are published
To whom data/document is available
All academic institutes and non-academic industrial institutes which are related to our studies will have access to our data after going through legal procedures.
Under which criteria data/document could be used
In case those people asking for data have the intention of optimizing the study an data and producing more results, access to data is allowed.
From where data/document is obtainable
Through sending an email to the corresponding author, data will be obtainable.
What processes are involved for a request to access data/document
In case someone asks for data, he must first get in contact with the corresponding author for his identity to be fully verified. Then if university allows propagation of data, it will be accessible in 3 months
Comments