

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 Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

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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+98 51 3858 3885

Email

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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ghanbarim951@mums.ac.ir

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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34591357

Phone

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Email

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

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

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Person responsible for updating data

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Full name of responsible person

Ali Manteghi

Position

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Email

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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 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