

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Influence of Lisdexamfetamine Mesilate (Vyas) in the treatment of premature ejaculation: A double-blind randomized clinical trial study

Protocol summary

Study aim

Influence of Lisdexamfetamine Mesilate (Vyas) in the treatment of premature ejaculation: A double-blind randomized clinical trial study

Design

A randomized clinical trial with parallel control group, double blind; Phase 2-3, on 46 patients; randomization is performed by using block randomization.

Settings and conduct

This study is performed in Farshchian Hospital in Hamadan. The intervention group is given a 30 mg capsule of Lisdexamfetamine Mesilate (Vyas) and the control group is given a placebo pill in the same form, and it is recommended that they take it at noon on a day when they are likely to be close to that day. Participants are asked to have intercourse at least twice a week for a month, and during the intervention do not use other methods such as topical creams or stop-motion techniques to increase ejaculation time and do not use condoms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age older and equal to 18 years Married and having at least 6 months of continuous sexual intercourse with a sexual partner Clinical diagnosis of PE based on PEDT questionnaire exclusion criteria: Taking drugs for sexual disorders during the study Having depression or other major psychiatric disorders during the study

Intervention groups

Intervention group : Patients receiving of 30 mg capsule Lisdexamfetamine Mesilate (Vyas) Control group: placebo group that is not distinguishable from the main drug.

Main outcome variables

increase Intra vaginal Ejaculatory Latency Time .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N10**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**

Update count: **0**

Registration date

2021-02-08, 1399/11/20

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-05-23, 1400/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of Lisdexamfetamine Mesilate (Vyas) in the treatment of premature ejaculation: A double-blind

randomized clinical trial study

Public title
Influence of Lisdexamfetamine Mesilate (Vyas) in the treatment of premature ejaculation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age older and equal to 18 yearse Married and having at least 6 months of continuous sexual intercourse with a sexual partner Clinical diagnosis of premature ejaculation (PE) based on premature ejaculation diagnosis test(PEDT)
Exclusion criteria:
Taking drugs for sexual disorders during the study2
Having depression or other major psychiatric disorders during the study

Age
From **18 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**
More than 1 sample in each individual
Number of samples in each individual: **23**
23 people are assigned to each group

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and the examining physician will not be aware of the patient's type of drug treatment, so the study will be performed in a double-blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2021-01-16, 1399/10/27

Ethics committee reference number
IR.UMSHA.REC.1399.870

Health conditions studied

1

Description of health condition studied
Premature ejaculation

ICD-10 code
F52.4

ICD-10 code description
Premature ejaculation

Primary outcomes

1

Description
Ejaculation Time

Timepoint
After every intercourse

Method of measurement
By the timer

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: 30 mg capsule of Lisdexamfetamine Mesilate (Vyas)

Category
Treatment - Drugs

2

Description
Control group: Placebo tablets

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital

Full name of responsible person

Mohammad Haghighi

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave

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haghighi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

Full name of responsible person

Dr.Mohammad Ahmadpanah

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Research center for behavioral disorders and substance abuse, Hamadan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information"

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable