Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Influence of modafinil in the treatment of premature ejaculation: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
Effect of modafinil in the treatment of premature ejaculation
Design
Randomized, double blind, parallel, Clinical trials with control group
Settings and conduct
Patients with premature ejaculation are randomly divided into two groups using envelopes containing colored cards and are treated with 100 mg modafinil or placebo for 4 weeks, 4 to 6 hours before intercourse
Participants/Inclusion and exclusion criteria
Patients with premature ejaculation who signed written informed consent and Currently, are not under further treatments
Intervention groups
The intervention group received moadfinil tablet and the control group received placebo tablet
Main outcome variables
Premature ejaculation profile score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090304001743N15**
Registration date: **2020-05-01, 1399/02/12**
Registration timing: **prospective**

Last update: **2020-05-01, 1399/02/12**
Update count: **0**
Registration date
2020-05-01, 1399/02/12

Registrant information
Name
Mohammad Haghighi
Name of organization / entity
Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 81 1827 4184
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2021-03-19, 1399/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Influence of modafinil in the treatment of premature ejaculation: a randomized, double-blind, placebo-controlled clinical trial

Public title
Influence of modafinil in the treatment of premature ejaculation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Premature ejaculation, based on the criteria of the DSM – 5 Married and having at least 6 months continuous sexual intercourse with a sexual partner Life long premature ejaculation Signed written informed consent

Exclusion criteria:
Currently under further treatments for premature ejaculation Erectile dysfunction or other sexual disorders Other psychiatric disorders such as Major depressive disorder bipolar disorders, anxiety disorders, post-traumatic stress disorders, or personality disorders Chronic diseases such as diabetes, hypertension, endocrine system disease

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
23 red cards and 23 blue cards are placed in a non-transparent packets, Each person picks up a packet, Each color is considered for a group

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, placebo, which is precisely in the form of a drug product, is administered randomly to the patients and explained to the patients that he or she may receive a drug or placebo. Therefore, the patient and the clinical caregiver are not aware of the type of product.The other person other than the investigator is responsible for the preparation of the drug and placebo boxes and the researcher is not aware of it. The investigator of the outcome is also unaware of the type of product.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Fahmideh Bulvar.Mahdieh street

City
Hamadan

Province
Hamadan

Postal code
65178

Approval date
2020-04-25, 1399/02/06

Ethics committee reference number
IR.UMSHA.REC.1399.081

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
Premature ejaculation profile score

Timepoint
Before the intervention, 4 weeks after the intervention

Method of measurement
Premature ejaculation profile Questionnaire

Secondary outcomes

1

Description
Intravaginal ejaculation latency time

Timepoint
Before the intervention,4 weeks s after intervention

Method of measurement
By a stopwatch

Intervention groups

1

Description
Intervention group: Modafinil tablets 100 mg 4 to 6 hours before intercourse

Category
Treatment - Drugs

2

Description
Control group: placebo tablets 4 to 6 hours before intercourse

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital
Full name of responsible person
Mohammad Haghighi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
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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
Hamedan 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
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Position
Professor of Psychiatry
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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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available