

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the effect adjuvant therapy of cranial electrical stimulation (CES) in premature ejaculation disorder patients.

Protocol summary

Study aim

Investigating the effect of adjutant therapy of cranial electrical stimulation (CES) on premature ejaculation disorder.

Design

A randomized, single-blind, placebo-controlled design of 30 patients trial. With simple randomization method.

Settings and conduct

The study was performed on patients referred to the Sexual Disorders Clinic of Taleghani Hospital. Patients with premature ejaculation disorder are included in the study. The standard treatment is prescribed to all patients. The intervention is perform in addition to standard drug treatment. Patients do not know whether they are in the placebo group or the test group.

Participants/Inclusion and exclusion criteria

inclusion criteria: Married men 18 to 65 years old with premature ejaculation disorder. exclusion criteria: Diabetes, hypertension and other diseases affecting premature ejaculation disorder.

Intervention groups

Cranial electrical stimulation with standard drug treatment. Inactive device with standard drug treatment (Placebo).

Main outcome variables

Rates of treatment; Duration of treatment; Need to take medicine; Side effects of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051657N1**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Hadi Delpasand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 1535

Email address

delpasand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect adjuvant therapy of cranial electrical stimulation (CES) in premature ejaculation disorder patients.

Public title

Investigating the effect of adjuvant therapy of cranial electrical stimulation (CES) on premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male sex. Married. Age 18 to 65 years. With premature ejaculation disorder.

Exclusion criteria:
Men with diabetes, hypertension and other diseases affecting premature ejaculation.

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

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method is used. Random allocation software is used to create a random sequence. The sequentially numbered, opaque sealed envelopes (SNOSE) method is used to allocation concealment.

Blinding (investigator's opinion)
Single blinded

Blinding description
To reduce bias , the single-blind method is used. In this method, the participant does not know which of the two groups of placebo or test belongs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address
Koodakyar Dead End, Shahid Shahriari square, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717434

Approval date
2021-06-15, 1400/03/25

Ethics committee reference number
IR.SBMU.MSP.REC.1400.147

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 by Premature Ejaculation Diagnostic Tool (Questionnaire)

Timepoint

Start of study and 3 weeks after intervention.

Method of measurement

Premature Ejaculation Diagnostic Tool (Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cranial electrical stimulation with a frequency of 250 Hz and intensity 3, for 3 weeks, 2 sessions per day and the duration of each session is 20 minutes. + Standard drug treatment(Tablet Sertraline 50 mg, 4 hours before sexual intercourse).

Category

Treatment - Devices

2

Description

Control group: Use the disabled device as the intervention group + Standard drug treatment(Tablet Sertraline 50 mg, 4 hours before sexual intercourse).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

(Ayatollah) Taleghani Educational Hospital-Tehran

Full name of responsible person

Mis Zarei

Street address

Aarabi St, Velenjak

City

Tehran

Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Fax
+98 21 2243 2570
Email
taleghanihospital@sbmu.ac.ir
Web page address
<https://taleghani.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi Ave, Velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9770
Email
Intl_office@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azadeh mazaheri
Position
Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Taleqani hospital, Arabi Ave, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Email
mazaheri.azadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azadeh mazaheri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Taleqani hospital, Arabi Ave, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Email
mazaheri.azadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hadi Delpasand
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Taleqani hospital, Arabi Ave, Velenjak
City
Tehran
Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Fax

Email

delpasand@gmail.com

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

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

make this available

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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