Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of sertraline and columipramine on premature ejaculation

Protocol summary

Study aim
Comparison of the efficacy of Sertraline and Clomipramin in the treatment of pre ejaculation

Design
This study included two intervention groups that were randomly assigned to treatment groups by blocking permutation method. The trial phase is 2-3. In each group, 30 patients will be treated.

Settings and conduct
This clinical trial is double-blind. That is, the evaluator and the patient are not aware of the type of medication they receive. This study will be conducted in the Golestan Hospital Psychiatry Department.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age between 16-60 years, Possibility to have sex twice in a week. Exclusion criteria: Presence of genital ulcer infection, systemic and neurological disorders, presence of severe psychiatric disorders, presence of narcotics and use of drugs.

Intervention groups
Intervention group 1: In the intervention group1, patients will be treated with sertraline 50 mg daily for three months. Then, the time of the LELT of all people (the average time at least three turns) at the start of the study (LELT0), as well as at 4, 9 and 12 weeks after the start of drug use by a person's partner and with a stopwatch, will be carefully measured and recorded.
Intervention group 2: In the intervention group2, patients will be treated with Clomipramin 50 mg daily for three months. Then, the time of the LELT of all people (the average time at least three turns) at the start of the study (LELT0), as well as at 4, 9 and 12 weeks after the start of drug use by a person's partner and with a stopwatch, will be carefully measured and recorded.

Main outcome variables
Duration from moment of insertion to the moment of ejaculation,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181117041682N3**
Registration date: **2019-04-27, 1398/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**
Update count: **0**

Registration date
2019-04-27, 1398/02/07

Registrant information

Name
Ahmad Fakhri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3622 4558

Email address
ahmad_fakhri@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison the effect of sertraline and columipramine on premature ejaculation

Public title
Comparison the effect of sertraline and columipramine on premature ejaculation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-60 years Possibility to have sex
Exclusion criteria:
The presence of genital ulcer infection Systemic and neurological disorders Severe psychiatric disorders Use of drugs
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups. Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly.
Blinding (investigator's opinion)
Double blinded
Blinding description
The medication will be prescribed by the assistants and given to the patients by the nurses at a psychiatric ward. The project executor is not aware of the prescriptions in each group. Also, patients are unaware of their treatment
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی جندی شاپور اهواز
Street address
Golestan Blvd, Ahvaz, Khoozestan
City
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Province
Khouzestan
Postal code
6135715794
Approval date
2018-11-22, 1397/09/01
Ethics committee reference number
IR.AJUMS.REC.1397.901

Health conditions studied

1

Description of health condition studied
Premature ejaculatuon
ICD-10 code
F52.4
ICD-10 code description
Premature ejaculation

Primary outcomes

1

Description
Duration from moment of insertion to the moment of ejaculation,
Timepoint
at the start of treatment, 4,9,12 weeks after treatment
Method of measurement
Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group1, patients will be treated with sertraline 50 mg daily for three months. Then, the time of the LELT of all people (the average time at least three turns) at the start of the study (LELT0), as well as at 4, 9 and 12 weeks after the start of drug use by a person's partner and with a stopwatch, will be carefully measured and recorded
Category
Treatment - Drugs

2

Description
Intervention group: In the intervention group2, patients will be treated with Clomipramin 50 mg daily for three months. Then, the time of the LELT of all people (the average time at least three turns) at the start of the

study (LELT0), as well as at 4, 9 and 12 weeks after the start of drug use by a person's partner and with a stopwatch, will be carefully measured and recorded

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Ahmad Fakhri

Street address

Ahvaz Golestan Hospital, Golestan Blvd,Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Ahvaz Junishapur University of Medical Science,Farvardin Blvd

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ahmad Fakhri

Position

Associate professorدانشیار

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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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
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
Not applicable

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