

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

##### Phone

+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

Ahvaz

#### Province

Khoozestan

#### 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

**Street address**

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 professor دانشیار

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Reza Emraee

**Position**

Resident

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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### Contact

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

## 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