

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Effect of sertraline on semen parameters in men with premature ejaculation

Protocol summary

Summary

The purpose of this study is to evaluate the effects of sertraline on semen parameters in men with premature ejaculation in Akhavan hospital clinic. In this double blind clinical trial 60 men with premature ejaculation (latency time less than 2min) who meet the inclusion criteria, will be randomly divided into 2 groups (case: 30 patients/sertraline 25mg/day, increasing dose to 50mg/day in first week, 3 months) and control group (30 patients/squeeze, start-stop technics/0, 4th, 8th weeks of study). Semen samples will be tested in 0, 3th week after clinic admission, 3 months after treatment and 3 weeks after completion of treatment. CASD and SCD technics will be used in semen evaluation and premature ejaculation will be evaluated in first visit and 4th, 8th and 12th week after treatment by self-reporting PE questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111178121N1**

Registration date: **2011-12-11, 1390/09/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-11, 1390/09/20

Registrant information

Name

Leila Sirati

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 1224 8960

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sertraline on semen parameters in men with premature ejaculation

Public title

Effect of sertraline on semen parameters in men with premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age18-40; married men without any history of known sexual disorders; no cigarettes smoking or any drug abuse or alcohol consumption; BMI: 20-28. Exclusion criteria: drug holding because of severe adverse effects of sertraline or no suitable effects (by patient); loss of patients; patient with current or past history of psychological disorders like depression or chemotherapy or radiotherapy; patient with current or past history of seizure or clinical varicocele ; patient with current or past history of chronic disease like diabetes, cirrhosis, uremia,...; desire to have a child in

time of study.

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of medical sciences

Street address

Kashan university of medical sciences.

City

Kashan

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

9037

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

Timepoint

0, 2nd week and 1st, 2nd, 3rd month after treatment

Method of measurement

self reporting questionnaire

2

Description

sperm count

Timepoint

first visit and 3 weeks after that/3 months after treatment and 3 weeks after Completion of treatment

Method of measurement

spermogram

Secondary outcomes

1

Description

drug advers effects

Timepoint

4th, 8th, 12th week

Method of measurement

self reporting

Intervention groups

1

Description

Control group: teaching squeeze, start-stop techniques in 0, 4th, 8th, 12th week after treatment.

Category

Treatment - Drugs

2

Description

Intervention group: tab sertraline 25mg/day, increasing dose to 50 mg/day in first week for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan hospital

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of
Medical Sciences

Full name of responsible person

Golam Ali Hamidi (PhD)

Street address

Kashan University of Medical Sciences

City

Kashan

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kashan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Leila Sirati

Position

resident of psychology

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gudarz Akkashe

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psychologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty