Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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)
Phone
+98 86 1224 8960
Email address
sirati_l@kaums.ac.ir

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 varichocele ; 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
Street address
Kashan University of Medical Sciences
City
kashan
Postal code
Phone
0O983614443023
Fax
Email
sirati_L@kaums.ac.ir , daesmaili@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Gudarz Akkashe
Position
psychologist
Other areas of specialty/work
Street address
Akhavan hospital
City
Kashan
Postal code
Phone
+98 36 1444 3023
Fax
Email
sirati_L@kaums.ac.ir
Web page address

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