

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of sexual side effects of treatment with Fluoxetine, Sertraline and Trazodone

Protocol summary

Summary

Objective: to compare the sexual side effects of treatment with Fluoxetine, Sertraline and Trazodone. Subjects are outpatients referred to psychiatric clinic who meet criteria of non psychotic major depressive disorder according to DSM-IV-TR with a score of 16 on Hamilton rating scale for depression. One hundred two patients are randomly divided into three groups and any group is treated with one of these antidepressants: Fluoxetine, Sertraline or Trazodone. Any group consists of 34 patients (17 men, 17 women). Patients are physically healthy with no concurrent medical illness and have been free of anti depressant (and other psychotropic) medication for at least 5 weeks before the initial visit. Sexual function questionnaire and HAM-D are filled for each patient in baseline. Clinician provides standard management in a clinical visit every 4 weeks while repeat measures of HAM-D and SFQ (sexual functioning questionnaire) up to 8-14 weeks after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810281522N3**

Registration date: **2010-06-24, 1389/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-24, 1389/04/03

Registrant information

Name

Habibolah Khazaie

Name of organization / entity

Department of Psychiatry, Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1838 4185

Email address

ha_khazaie@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2009-12-01, 1388/09/10

Expected recruitment end date

2010-03-01, 1388/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sexual side effects of treatment with Fluoxetine, Sertraline and Trazodone

Public title

Comparison of side effects of antidepressants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: major depressive disorder, being physically healthy. Exclusion criteria: concurrent active medical illness, antidepressant and anti psychotic medication for at least 5 weeks before initial study visit.

Age

No age limit

Gender

Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comittee of Kermanshah University of Medical Sciences and Health Servises

Street address

Shahid Beheshti boulevard

City

Kermanshah

Postal code

Approval date

2009-11-30, 1388/09/09

Ethics committee reference number

37566/420/7/پ

Health conditions studied

1

Description of health condition studied

Major depression disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Sexual side effects

Timepoint

8-14 weeks

Method of measurement

sexual function questionnaire (sfq)

Secondary outcomes

1

Description

Response to treatment

Timepoint

4 weeks

Method of measurement

HAMILTON rating scale

Intervention groups

1

Description

Fluoxetine 20-40mg

Category

Treatment - Drugs

2

Description

Sertraline 50-200mg

Category

Treatment - Drugs

3

Description

Trazodone 200-300mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital clinic

Full name of responsible person

Nastaran Rezaei payam

Street address

Farabi Hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Shahid Beheshti Blvd
City
 Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Research deputy of Kermanshah 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
 Farabi hospital, Kermanshah university of medical science
Full name of responsible person
 Dr Habibolla Khazaie
Position
 psychiatrist/associate professor/chairman
Other areas of specialty/work
Street address
 Farabi hospital
City
 Kermanshah
Postal code
 6719851151
Phone
 +98 83 1826 4512
Fax
Email
 ha_khazaie@kums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Kermanshah university of medical science
Full name of responsible person
 Dr. Habiballah Khazaie

Position
 National board of psychiatry
Other areas of specialty/work
Street address
 Farabi Hospital
City
 Kermanshah
Postal code
 6719851151
Phone
 +98 83 1826 4512
Fax
Email
 ha_khazaie@kums.ic.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Kermanshah university of medical sciences
Full name of responsible person
 Nastaran Rezaie payam
Position
 resident of psychiatry
Other areas of specialty/work
Street address
 Farabi hospital, Ashier blvd
City
 Kermanshah
Postal code
Phone
 +98 83 1826 4512
Fax
Email
 nrezaie@kums.ac.ir
Web page address
 kums.ac.ir

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