Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of efficacy of risperidone addition to fluoxetine in obsessive compulsive patients

Protocol summary

Summary

To study the efficacy of addition of risperidone to fluoxetine in obsessive compulsive disorder, we will choose 60 subjects among outpatient clients seeking help in our psychiatric clinic who according to DSM-IV-TR meet the criteria for obsessive compulsive disorder and on Yale Brown rating scale (YBOCS) score at least 16. The subjects will be randomly divided into two groups: one group will be treated with fluoxetine-risperidone and the other with fluoxetine –placebo. Each group consists of 30 subjects in whom psychotic disorders, substance abuse and suicidal ideation have been ruled out and age between 18-65 years. The YBOCS questionnaire will be filled for each patient at the beginning of the study and after 6-12 weeks from treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103083010N2**
Registration date: **2011-04-18, 1390/01/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-18, 1390/01/29

Registrant information

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Faeze Tatari
Name of organization / entity
Kermanshah University of Medical Sciences and Health Services
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Kermanshah University of Medical Sciences and Health Servises

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy of risperidone addition to fluoxetine in obsessive compulsive patients

Public title

The efficacy of combination of risperidone and fluoxetine in obsessive compulsive patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obsessive compulsive disorder, New case , age>18, age<65, Yale Brown rating scale >16.
Exclusion criteria: substance abuse, comorbid of psychotic disorder, suicidal ideation, Yale Brown rating.

Age

From **18 years** old to **65 years** old

Gender

Both

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
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Comitte of Kermanshah University of Medical Sciences and Health Servises
Street address
Shahid Beheshti Blvd, 2th Building of Kermanshah University
City
Kermanshah
Postal code
6714673159
Approval date
2010-11-09, 1389/08/18
Ethics committee reference number
9881/420/7/پ

Health conditions studied

1

Description of health condition studied
Obsessive-compulsive disorder
ICD-10 code
F42.8
ICD-10 code description
Anxiety disorder

Primary outcomes

1

Description
Response to treatment
Timepoint
Before treatment, 6weeks after treatment , 12weeks after treatment
Method of measurement
Obsessive compulsive qustioner (Y-Bocs)

Secondary outcomes

1

Description
Clinical side effects
Timepoint
6 and 12 weeks after treatment
Method of measurement
According to patients report

Intervention groups

1

Description
Intervention group: risperidone is started at 0.5 mg/d in the first week and then is elevated to 1 mg/d in the second week and is continued until the end of the third month.
Category
Treatment - Drugs

2

Description
Control group: identical to that of risperidone.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital clinic
Full name of responsible person
Dr. Tatari
Street address
Farabi Hospital of Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services
Full name of responsible person
Dr. Farid Najafi
Street address
Shahid Beheshti boulevard
City
Kermanshah
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, Kermanshah University of Medical Sciences and Health Services
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
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Full name of responsible person
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Person responsible for updating data

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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