Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Granisetron in the treatment of obsessive-compulsive disorder: a double-blind, placebo controlled trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of granisetron would improve psychopathology in subjects with OCD treated with fluvoxamine. 40 patients with chronic DSM-IV-diagnosed OCD will receive fluvoxamine(200 mg/day) combined with either placebo (N=20) or 2 mg/day granisetron(N=20) for 8 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Yale-Brown obsessive compulsive scale(Y-B ocs).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202041556N32**
Registration date: **2012-02-06, 1390/11/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-06, 1390/11/17

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Granisetron in the treatment of obsessive-compulsive disorder: a double-blind, placebo controlled trial

Public title

Granisetron in the treatment of obsessive-compulsive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:Age between 18-60; Diagnosis of OCD based on DSM IV; Minimum Score of 21 on YALE-BROWN Obsessive-Compulsive Scale- Exclusion Criteria: Substance dependence; IQ <70; any other mental disorder on axis I; Any serious cardiac, renal or hepatic disease ; receiving psychotropic medications during the last 6 weeks ; pregnancy orbreast feeding; rising liver transaminases to three times the upper limit of normal or higher

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2011-04-04, 1390/01/15

Ethics committee reference number

10387

Health conditions studied

1

Description of health condition studied

Obsessive- Cumpulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive- Cumpulsive Disorder

Primary outcomes

1

Description

Severity of symptoms of OCD

Timepoint

Baseline and weeks 2-4-6-8 after beginig of treatment

Method of measurement

by Y-BOCS Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Tablet fluvoxamine (200 mg/day) combined with 2 mg/day of Tablets granisetron as intervention group for 8 weeks

Category

Treatment - Drugs

2

Description

Tablet fluvoxamine (200 mg/day) combined with placebo as control group for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

Street address

South kargar street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
Position
Ph.D. of Clinical Psychopharmacology
Other areas of specialty/work
Street address
Roozbeh Hospital, South Kargar street
City
Tehran
Postal code
Phone
+98 21 5541 2222
Fax
Email
s.akhond@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
Position
Ph.D. of Clinical Psychopharmacology
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Street address
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Web page address

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