

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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 or breast 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- Compulsive Disorder

#### ICD-10 code

F42

#### ICD-10 code description

Obsessive- Compulsive 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**

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**Phone**

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**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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## 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*