

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### ondansetron as adjuvant therapy in the treatment of OCD: a double blind randomized trial

#### Protocol summary

##### Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of ondansetron would improve psychopathology in subjects with OCD treated with fluvoxamine. 40 patients with chronic DSM-IV-diagnosed OCD will receive fluvoxamine(100 mg/day) combined with either placebo (N=20) or 8mg/day ondansetron(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: **IRCT201204271556N41**  
Registration date: **2012-04-28, 1391/02/09**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-04-28, 1391/02/09

##### 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

2012-04-29, 1391/02/10

##### Expected recruitment end date

2012-07-31, 1391/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

ondansetron as adjuvant therapy in the treatment of OCD: a double blind randomized trial

##### Public title

ondansetron in the treatment of obsessive-compulsive disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: 1-Age between 18-60, 2-Diagnosis of OCD based on DSM IV 3 , Minimum Score of 21 on YALE-BROWN Obsessive-Compulsive Scale- Exclusion Criteria:1- Substance dependence,2- IQ <70,3-any other mental disorder on axis I, 4-Any serious cardiac, renal or hepatic disease ,5- receiving psychotropic medications during the last 6 weeks 6- pregnancy or breast feeding 7- 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

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Keshvarz Blvd

##### City

Tehran

##### Postal code

#### Approval date

2012-02-20, 1390/12/01

#### Ethics committee reference number

13232

## 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

Y\_BOCS( Yale-Brown obsessive compulsive scale)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Tablet fluvoxamine (100 mg/day) combined with 8 mg/day of Tablets ondansetron as intervention group for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Tablet fluvoxamine (100 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

Dr. Shahin Akhondzadeh

##### Street address

South Kargar Sreet

##### 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

Keshvarz 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

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Prof. Shahin Akhondzadeh  
**Position**  
Prof. of Clinical Psychopharmacology  
**Other areas of specialty/work**  
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s.akhond@sina.tums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

### Contact

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Tehran University of Medical Sciences  
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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*