

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Amantadin as adjuvant therapy in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of Amantadin would improve psychopathology in subjects with OCD treated with fluvoxamine. 50 patients with chronic DSM-5- diagnosed OCD will receive fluvoxamine (100 mg BID) combined with either placebo (N=25) or 100 mg/day Amantadin (N=25) for 10 weeks. Patients will be assessed by a psychiatrist at baseline and after 2, 4, 6, 8 and 10 weeks after the medication started. OCD severity will be assessed by the Yale-Brown obsessive compulsive scale (Y-B ocs)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705191556N99**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

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

2017-05-22, 1396/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Amantadin as adjuvant therapy in the treatment of moderate to severe OCD: a double blind randomized trial with placebo control

Public title

Amantadin as adjuvant therapy in the treatment of moderate to severe OCD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Age between 18-60 years old; 2- Diagnosis of OCD based on DSM-5; 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: 50

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

Tehran University of Medical Sciences, Keshvarz Blvd.

City

Tehran

Postal code**Approval date**

2017-05-04, 1396/02/14

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2114

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, 10 after beginig of treatment

Method of measurement

Y_BOCS(Yale-Brown obsessive compulsive scale)

Secondary outcomes

empty

Intervention groups**1****Description**

Fluvoxamine 100 mg BID+ Amantadin 100mg/day for 10 weeks as intervention group

Category

Treatment - Drugs

2**Description**

Fluvoxamine 100 mg BID + placebo for 10 weeks as control group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Sreet

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Tehran University of Medical Sciences, 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

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Web page address**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**Street address**

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City

Tehran

Postal code**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