

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

N-Acetylcysteine as adjuvant therapy in moderate to severe OCD : a double blind randomised clinical trial

Protocol summary

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Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of N-Acetylcysteine would improve psychopathology in subjects with OCD treated with fluvoxamine. 50 patients with chronic DSM-V- diagnosed OCD will receive fluvoxamine (100 mg/day) combined with either placebo (N=25) or 2000 mg/day N-Acetylcysteine (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)

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405271556N60**

Registration date: **2014-05-27, 1393/03/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-27, 1393/03/06

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

Scientific title

N-Acetylcysteine as adjuvant therapy in moderate to severe OCD : a double blind randomised clinical trial

Public title

N-Acetylcysteine 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 V 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

N/A

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

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2014-05-01, 1393/02/11

Ethics committee reference number

24318

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 2-4-8-10 after beginig of treatment

Method of measurement

Y_BOCS

Secondary outcomes

empty

Intervention groups

1

Description

fluvoxamine 100 mg/day+ N-Acetyl cysteine 200 mg/day for 10 weeks as intervention group

Category

Treatment - Drugs

2

Description

Fluvoxamine 100 mg/day + 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

Prof. Shahin Akhondzadeh

Street address

South Kregar street, Roozbeh Hospital

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

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**

South Kargar street; Roozbeh Hospital

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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