Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of N-Acetyle-Cysteine 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-Acetyle-Cysteine (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 b the Yale-Brown obsessive compulsive scale(Y-B ocs)

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

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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

Scientific title

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

Public title

N-Acetyle-Cysteine 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- Cumpulsive 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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Prof. Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
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Person responsible for updating data

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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