Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

N-Acetylcysteine Augmentation in Treatment of Refractory Obsessive-Compulsive Disorder, a double blind randomized placebo controlled clinical trial

Protocol summary

Summary

The sample of this interventional study includes 40 subjects with refractory OCD. In the parallel assignment, they will be randomly allocated into two groups. One group is a placebo control. The second group takes augmentation of N-Acetyl cystein. It is a double blind study that the subject, investigators, outcomes assessor are blind to the groups. The primary purpose of this study is treatment. The Experimental group will receive N-Acetylcysteine augmentation, at a standard dose titrated up to 1200 mg within three weeks, in addition to the medication regimen they are on at enrollment. Placebo group will receive placebo, formulated to be indistinguishable from N-Acetylcysteine, in addition to the medication regimen they are on at study enrollment. The ages eligible for Study is 10 to 20 years and it includes both genders

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103243930N4**
Registration date: **2011-04-11, 1390/01/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-11, 1390/01/22

Registrant information

Name

Ahmad Ghanizadeh

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

N-Acetylcysteine Augmentation in Treatment of Refractory Obsessive-Compulsive Disorder, a double blind randomized placebo controlled clinical trial

Public title

N-Acetylcysteine Augmentation in Treatment of Refractory Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria are: DSM-IV diagnosis of OCD; symptoms of at least 1 year duration, moderate to severe OCD symptoms (Y-BOCS > 16), and failure of an adequate trial of an SSRI. Exclusion Criteria are: primary diagnosis of a psychotic disorder, active substance abuse or dependence, unstable medical condition, prior

exposure to N-Acetylcysteine, pregnancy, breastfeeding, or intent to become pregnant during study, evidence of active liver disease, seizure disorder, and active suicidal ideation.

Age
From **10 years** old to **20 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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 Shiraz University of Medical Sciences

Street address
Zand Street, Shiraz University of Medical sciences-Vice-chancellery of Research Affairs

City
Shiraz

Postal code

Approval date
2010-12-30, 1389/10/09

Ethics committee reference number
Ct-89-2147

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
Yale-Brown Obsessive-Compulsive Scale

Timepoint
every 2 weeks for 10 weeks

Method of measurement
Interview

Secondary outcomes

1

Description
Clinical Global Impression

Timepoint
every 2 weeks for 10 weeks

Method of measurement
Self-report

Intervention groups

1

Description
N-Acetylcysteine (at a standard dose titrated up to 1200 mg within the first week) + SSRI

Category
Treatment - Drugs

2

Description
Placebo + SSRI

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Street address
Chamran Street, Hafez hospital

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person
Gholam Reza Hatam
Street address
Zand Street, Shiraz University of Medical sciences-Vice-chancellery of Research Affairs
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shiraz 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
Shiraz University of Medical sciences
Full name of responsible person
Ahmad Ghanizadeh
Position
M.D.
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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