Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

N-Acetylcysteine (NAC) augmentation in the treatment of symptoms and cognitive function among patients with obsessive-compulsive disorder A double-blind placebo-controlled, randomized clinical trial

Protocol summary

Study aim
Comparison of treatment effect of N-Acetylcysteine (NAC) plus Sertraline with Placebo and Sertraline on OCD patients

Design
Two arm parallel group randomized trial with blinded postoperative care and outcome assessment. Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Settings and conduct
OCD outpatients who come to psychiatric clinics of Iran University of Medical Sciences will be recruited. Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. All of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Participants/Inclusion and exclusion criteria
Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 years old and sign consent form. they should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will evaluate for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Intervention groups
NAC plus Setraline and Placebo plus Sertraline

Main outcome variables
Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym
OCD

IRCT registration information
IRCT registration number: **IRCT20170123032145N7**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date
2023-06-08, 1402/03/18

Registrant information

Name
Mohammadreza Shalbafan

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6655 1665

Email address
shalbafan.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-06, 1402/04/15

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
N-Acetylcysteine (NAC) augmentation in the treatment of symptoms and cognitive function among patients with obsessive-compulsive disorder A double-blind placebo-controlled, randomized clinical trial

Public title
NAC for treatment of Obsessive-Compulsive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 year old They should sign the consent form
Exclusion criteria:
They should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. Therefore, a table including 4: 1 blocks with random allocation of 2 numbers for each group will be given to a person other than recruiter/ evaluator and they will mark the medication box based on this numbers.
Blinding (investigator's opinion)
Triple blinded
Blinding description
To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-05-23, 1402/03/02
Ethics committee reference number
IR.IUMS.REC.1402.119

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 obsessive-compulsive disorder
Timepoint
Weeks: 0, 4, 8 and 12
Method of measurement
Yale-Brown Obsessive Compulsive Scale(YBOCS)

Secondary outcomes

1

Description
Working Memory
Timepoint
Weeks: 0, 12
Method of measurement
Wisconsin Test

2

Description
Selective Attention
Timepoint
Weeks: 0, 12
Method of measurement
d۲ Selective Attention Test

Intervention groups

1

Description
Intervention group: Sertraline(Tab) 200 mg/day plus NAC (Tab) 2400mg per day for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Sertraline(Tab) 200 mg/day plus placebo(Tab) for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Psychiatric Hospital
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Tehran- Karaj Highway 7 km
City
Tehran
Province
Tehran
Postal code
1398913151
Phone
+98 21 4450 3395
Email
Shalbafan.mr@iums.ac.ir
Web page address
http://iph.iums.ac.ir/

2

Recruitment center
Name of recruitment center
Tehran Psychiatric Institute
Full name of responsible person
Dr Mohammadreza Shalbafan
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1665
Email
Shalbafan.mr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Reza Falak
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
mhrc@iums.ac.ir
Grant name
High quality articles grant
Grant code / Reference number
1401-4-99-25244
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammadreza Shalbafan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Hemmat Exp. way, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1445613111

Phone
+98 21 6655 1665

Fax
+98 21 6655 1665

Email
shalbafan.mr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammadreza Shalbafan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Hemmat Exp. way, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 6655 1665

Fax
+98 21 6655 1665

Email
shalbafan.mr@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammadreza Shalbafan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Hemmat Exp. way, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 6655 1665

Fax
+98 21 6655 1665

Email
shalbafan.mr@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Data about main outcome of study will be published

When the data will become available and for how long
2026

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
For scientific goals

From where data/document is obtainable
shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

What processes are involved for a request to access data/document
Sending an E-mail and reason of request

Comments