Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of adding N-acetylcysteine to the usual treatments of schizophrenia on the positive, negative and cognitive symptoms of patients with schizophrenia admitted

Protocol summary

Study aim
The effect of adding NAC to common treatments for schizophrenia on their positive, negative and cognitive symptoms

Design
Clinical trial with control group, double-blind, randomized, phase 2, on 70 patients. Random number table was used for randomization.

Settings and conduct
Patients diagnosed with schizophrenia referred to Khorshid Hospital who meet the inclusion criteria are divided into 2 groups of 35 people.One group is treated with NAC and other group with placebo.it is a double-blind study with double random block method so that patients and researchers do not know how to group.NUCOG, SANS,SAPS is taken from patients at the beginning,at the end of the first month and second month. The level of environmental Glutathion is measured at the beginning and end of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with schizophrenia with an age-19- 65 years who have passed the acute phase, diagnosis of schizophrenia according to DSM 5 criteria by a psychiatrist, education of at least five classes. No entry conditions; Pregnancy and lactation, substance abuse, severe physical illness, NAC prohibition, intellectual disability, ECT 6 months before or during the study, patients treated with nitroglycerin, insulin, Chloroquine, more than 200 mg selenium, anticoagulants except aspirin and NSAIDs.

Intervention groups
In the intervention group, patients receive 600 mg of N-acetylcysteine daily for 2 months with the usual treatment and in the control group, they receive the usual placebo treatment.

Main outcome variables
Mean NUCOG total score and its domains, Negative Symptom Scale, Positive Symptom Scale, Duration of disease, Age, Sex, Regenerated Glutathione level, Drug side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201119049445N2**
Registration date: **2022-06-09, 1401/03/19**
Registration timing: **prospective**

Last update: **2022-06-09, 1401/03/19**
Update count: **0**

Registration date
2022-06-09, 1401/03/19

Registrant information

Name
Hajar Salimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3222 2127

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-21, 1401/03/31

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adding N-acetylcysteine to the usual treatments of schizophrenia on the positive, negative and cognitive symptoms of patients with schizophrenia admitted

Public title
The effect of adding N-acetylcysteine to the usual treatments of schizophrenia in improving the symptoms in patients referred to the ward and clinic of Khorshid Hospital in 1401
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with schizophrenia between the ages of 19 and 65 who have undergone the acute phase (the onset of the acute phase is assessed by a psychiatrist and the project resident) Diagnosis of schizophrenia based on DSM 5 criteria by a psychiatrist Have at least five classes of education
Exclusion criteria:
Pregnancy and lactation Substance abuse Severe physical illness Contraindications to the use of N-acetylcysteine Existence of intellectual disability Receive ECT 6 months before or during the study Patients treated with nitroglycerin Patients treated with insulin Patients treated with chloroquine Patients treated with more than 200 mg of selenium Patients treated with anticoagulants except aspirin and NSAIDs
Age
From **19 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random blocks method that after sampling people are randomly divided into two equal groups by a table of random numbers and the codes are done by hiding the code card in thick envelopes (Concealed allocation) one of them The N-acetylcysteine group is randomly assigned to the current treatment and the other to the placebo group with the current treatment is randomly assigned.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, in collaboration with the Faculty of Pharmacy of Isfahan University of Medical Sciences, drugs and placebo produced in the same form and with specific codes for each category are provided to patients and after the study is decoded.During this study, patients and the main researcher are kept blind from the study group
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences.
Street address
No. 20, Jaleh dead end, Bahman alley, 2nd Apadana street
City
Esfahan
Province
Isfehan
Postal code
8166783991
Approval date
1991-12-29, 1370/10/08
Ethics committee reference number
IR.ARI.MUI.REC.1401.013

Health conditions studied

1

Description of health condition studied
Patients with schizophrenia who have undergone an acute phase
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Improve cognitive function
Timepoint
Before the start of the study and 4, 8 weeks after taking N-acetylcysteine
Method of measurement
Average total score of NUCOG questionnaire and its areas

2

Description
Improve the negative symptoms of schizophrenia
Timepoint
Before the start of the study and 4, 8 weeks after taking N-acetylcysteine
Method of measurement
Scale for the Assessment of negative Symptoms

3

Description
Improve the positive symptoms of schizophrenia
Timepoint
Before the start of the study and 4, 8 weeks after taking N-acetylcysteine
Method of measurement
Scale for the Assessment of Positive Symptoms

Secondary outcomes

1

Description
peripheral blood glutathione leve
Timepoint
Before the intervention and two months after the intervention
Method of measurement
Blood sampling and measurement of glutathione levels with glutathione assy kit

Intervention groups

1

Description
Intervention group: N-acetylcysteine at a dose of 600 mg daily in effervescent tablets for two months
Category
Treatment - Drugs

2

Description
Control group: One placebo daily for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Hajar Salimi
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No. 105, Shahid Dastgheib Boulevard, Ostandari Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mojgan Mortazavi
Street address
Vice Chancellor for Research and Technology ,Building No. 4, Isfahan University of Medical Sciences and Health Services ,Hezar Jerib
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hajar Salimi
Position
Assistant professor

Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable