

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 Glutathione 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)

Phone

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Email address

salimi85ha@gmail.com

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

Isfahan

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 assay 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

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Vice Chancellor for Research and Technology
, Building No. 4, Isfahan University of Medical Sciences
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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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