Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of N-acetylcysteine and standard treatment on anxiety score in patients with generalized anxiety disorder

Protocol summary

Study aim
The effect of N-acetylcysteine in patients with generalized anxiety disorder
Design
Clinical trial with control group, with parallel groups, not blind, randomized, phase 3, on 100 patients. Accidental block randomization
Settings and conduct
Patients with Generalized Anxiety Disorder refer to Razi Hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with GAD disorder diagnosed by a psychiatrist based on DSM-V criteria and spit-zer questionnaire. Non-inclusion criteria: Patients with hepatic encephalopathy, asthma, gastric hemorrhage and fluid overload; Taking anticonvulsant drugs; Other Mental disorders such as autism, seizures and chronic diseases; Pregnant and lactating women; Inability to understand and sign consent form
Intervention groups
Intervention group:Includes 50 patients who receive N-acetylcysteine in addition to routine treatment for 2 months. Control group: Includes 50 patients who receive only routine treatment of the disease prescribed by a psychiatrist.
Main outcome variables
Anxiety score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150706023083N5**
Registration date: **2020-08-09, 1399/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-09, 1399/05/19**
Update count: **0**
Registration date
2020-08-09, 1399/05/19

Registrant information
Name
Haleh Rezaee
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-05, 1399/04/15
Expected recruitment end date
2021-07-06, 1400/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of N-acetylcysteine and standard treatment on anxiety score in patients with generalized anxiety disorder

Public title
The effect of N-acetylcysteine in GAD
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with GAD disorder at the discretion of a psychiatrist based on DSM-V criteria and Spit-zer questionnaire

Exclusion criteria:

Patients with hepatic encephalopathy , asthma, gastric hemorrhage and fluid overload Taking anticonvulsant drugs Other Mental disorders such as autism, seizures and chronic diseases Pregnant and lactating women Inability to understand and sign consent

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using block of size 4.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Tabriz University of Medical Science

Street address

No 20, Safa avenue, Besaat street, Mirdamad

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Tabriz

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East Azarbaijan

Postal code

5166956547

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.TBZMED.REC.1399.301

Health conditions studied

1

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety score

Timepoint

On arrival and after 2, 4, 6, 8 weeks after receiving medicine

Method of measurement

Spit-Zer Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Including 50 patients who, in addition to receiving standard treatment for anxiety disorder, receive N-acetylcysteine for 2 months at a daily dose of 600 mg .

Category

Treatment - Drugs

2

Description

Control group: Includes 50 patients who receive only standard treatment for the disease.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Clinic of Razi Hospital

Full name of responsible person

Dr Zahra Moosavi

Street address

Sheykh Mohammad Khiyabani Ave., Bakeri blvd., Elgoli, Tabriz

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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Sanaz Hamedyazdan
Street address
Faculty of Pharmacy, 6th floor, Department of Clinical Pharmacy, Daneshgah street, Tabriz
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Haleh Rezaee
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Assistant Professor of Clinical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There isn't more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available