

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 2250

Email address

rezaeeha@tbzmed.ac.ir

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

City

Tabriz

Province

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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5167846184

Phone

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Email

librazi@tbzmed.ac.ir

2

Recruitment center

Name of recruitment center

SHeykh Al-Rais clinic

Full name of responsible person

DR Zahra Moosavi

Street address

Sheikh Al-Rais Building , Azadi Street, not far from
Golgasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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