

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluating the Effectiveness of Adjunctive Therapy Using Folic Acid in Reducing Negative Symptoms of Male Schizophrenia Patients

Protocol summary

Study aim

This study aimed to evaluate the effect of folic acid as an adjunct in reducing the negative symptoms of hospitalized and outpatient male schizophrenia patients.

Design

A Placebo-Controlled, Double-Blind, Randomized Clinical Trial Performed on 30 Male Patients

Settings and conduct

5 Azar Gorgan Psychiatric Hospital in 2022

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Schizophrenia Diagnosis Based on V-DSM Diagnostic Criteria, Males Aged Between 18 and 50 years, No Extrapyramidal Symptoms Exclusion Criteria: Clinically Prominent Neurological or Organic Diseases, Abnormalities in Previous Tests, Presence of Another Major I-Axis Diagnosis, IQ Less than 70 Based on Standardized Tests, History of Drug Use (Excluding Nicotine and Caffeine), ECT in the Past Two Weeks, Oral Antipsychotics in the Past Week, Long-Acting Antipsychotics in the Past Month

Intervention groups

Treated with 5 mg folic acid tablets for 6 weeks In the control group, the drug will be used according to the previous procedure

Main outcome variables

Improving the Quality of Life and Reducing Negative Symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N55**

Registration date: **2022-07-09, 1401/04/18**

Registration timing: **prospective**

Last update: **2022-07-09, 1401/04/18**

Update count: **0**

Registration date

2022-07-09, 1401/04/18

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effectiveness of Adjunctive Therapy Using Folic Acid in Reducing Negative Symptoms of Male Schizophrenia Patients

Public title

Effect of Folic Acid in Reducing Negative Symptoms of Male Schizophrenia Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Schizophrenia Diagnosis Based on V-DSM Diagnostic Criteria
Absence of Extrapyrimal Symptoms
Male
Gender
Age Between 18 to 50 Years Old
Completing Informed Consent to Participate in the Study

Exclusion criteria:

Clinically Prominent Neurological or Organic Disease
Presence of Another Major I-Axis Diagnosis Based on V-DSM
Abnormality in Previous Tests
IQ Less than 70
Based on Standardized Tests
History of Drug Use (Excluding Nicotine and Caffeine)
ECT in the Past Two Weeks
Oral Antipsychotics in the Past Week or Long-Acting Antipsychotics in the Past Month

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

This is how random numbers are prepared with the help of Randomize.com. 30 envelopes, a number of aluminum-wrapped envelopes (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the random sequences created is registered on a card and the cards are inserted into the deck. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants to the study, one of the envelopes of the letter is opened and the envelopes containing the number of odd or even are assigned to the control or intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects and clinical caregivers are fully aware of the subject of research and the purpose and process of the study, and after filling out the consent and according to the entry conditions, will enter the study of the contents of the envelope and to which group they are assigned (control and intervention) (Because they do not predict the outcome) will be unaware. Take it and give it to the investigator

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Gorgan - the beginning of Shast Kola Road - Higher Education Complex of the Philosophical Deceased - Gorgan Medical School.

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-05-23, 1400/03/02

Ethics committee reference number

IR.GOUMS.REC.1400.044

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Reducing Negative Symptoms

Timepoint

Before the intervention and after 6 weeks of drug use

Method of measurement

With PANSS test questionnaire, the process of improvement and reduction of symptoms is measured

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group received 5 mg folic acid tablets for six weeks. Symptom severity was evaluated according to PANSS criteria at baseline

and weeks 2, 4, and 6. Data were then analyzed using SPSS.

Category

Treatment - Drugs

2**Description**

Control group: The controls received a placebo for six weeks. Symptom severity was evaluated according to PANSS criteria at baseline and weeks 2, 4, and 6. Data were then analyzed using SPSS.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

5 Azar Gorgan Psychiatric Hospital

Full name of responsible person

فاطمه ضيا

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5Th Azar Ave. Gorgan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehran Hosseini

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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

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Elahe Mehdi Zade

Position

دانشجو

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

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Person responsible for updating data

Contact

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Position
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Latest degree
Medical doctor
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available