

# 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

nejatir2@mums.ac.ir

##### 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 ضیا

**Street address**

5Th Azar Ave. Gorgan

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4917763681

**Phone**

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**Email**

raikaravan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Mehran Hosseini

**Street address**

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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**

General Practitioner

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Raikaravan@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Leila Kashani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Gorgan University of Medical Sciences  
**Full name of responsible person**  
الهه مهدی زاده  
**Position**  
Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Hirkan Blv., Gorgan  
**City**  
Gorgan  
**Province**  
Golestan  
**Postal code**

## 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