

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effectiveness of memantine in improving cognitive deficits, quality of life and reducing the negative symptoms of schizophrenia patients

#### Protocol summary

Cognitive assessment, quality of life and negative symptoms

##### Study aim

The effect of memantine on improving cognitive deficits and quality of life and reducing the negative symptoms of schizophrenia

##### Design

Phase 3 A clinical trial with a control group, with parallel groups, double-blind, randomized, selected on 40 patients over a period of 12 weeks. Random number argument will be used to create a random sequence. Numbers Pairs will be assigned to the intervention group and odd numbers to the control group

##### Settings and conduct

The study in Zanjan Hakim Center, Samples will be Simple random method assigned to the intervention and control groups. a sample size of 40 patients with schizophrenia will be performed for 12 week

##### Participants/Inclusion and exclusion criteria

Inclusion : patients with diagnostic criteria (DSM-5) of schizophrenia and at least two years after diagnosis Age 18 to 50 years Receive a fixed dose of antipsychotics for at least 8 weeks and for 4 weeks before enrollment Continue treatment with at least one antipsychotic drug during the study Exclusion: Outstanding neurological or organic disease in clinical & laboratory studies Another diagnosis in axis I Coexistence with mental retardation Drug addiction or abuse (except nicotine and caffeine) Inability to communicate High risk of suicide Receive ECT in the last two weeks History of memantine sensitivity kidney disease Pregnancy & lactation Do not use safe contraception in women

##### Intervention groups

In addition to routine treatment for schizophrenia, memantine tablets will be prescribed for the intervention group. Treatment with 5 mg memantine will be started first and increased 5 mg weekly to 20 mg, then the 20 mg dose will be continued for two months. The control group will receive a placebo in addition to the routine treatment

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200918048751N1**

Registration date: **2020-10-30, 1399/08/09**

Registration timing: **prospective**

Last update: **2020-10-30, 1399/08/09**

Update count: **0**

##### Registration date

2020-10-30, 1399/08/09

##### Registrant information

##### Name

Alireza Armanikian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3301 8149

##### Email address

dr.armmani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-01-09, 1399/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of memantine in improving cognitive deficits, quality of life and reducing the negative symptoms of schizophrenia patients

**Public title**

The effect of memantine in improving cognitive deficits, quality of life and reducing the negative symptoms in schizophrenic patients.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having diagnostic criteria (DSM-5) for patients with schizophrenia and at least two years after diagnosis Age 18 to 50 years Receive a fixed dose of antipsychotic for at least 8 weeks and for 4 weeks before enrollment Continue treatment with at least one antipsychotic drug during the study

**Exclusion criteria:**

Outstanding neurological or organic disease in clinical and laboratory studies Existence of another axis-based diagnosis (DSM-5) Coexistence with mental retardation Drug addiction or abuse (except nicotine and caffeine) Inability to communicate High risk of suicide Receive ECT in the last two weeks History of memantine sensitivity Having kidney disease Pregnancy and lactation Do not use safe contraception in women

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible individuals will be randomly assigned to two groups. For this purpose, first a random sequence will be created from the table of random numbers. Then the extracted even numbers will be assigned to the intervention group and the odd numbers will be assigned to the control group. This process will continue to reach the sample size.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants and research physicians will not be aware of the distribution of the drug and placebo, which are similar in color, size, shape, and odor to the original drug. To hide the drugs and placebo will be placed in a sealed matte envelope numbered in a row. Envelopes will be prepared by a non-research person.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of zanzan University of Medical Sciences

**Street address**

Therapeutic and Psychiatric Center, Ark Square, Shahid Dr. Beheshti Educational

**City**

Zanzan

**Province**

Zanzan

**Postal code**

45136-15788

**Approval date**

2020-08-15, 1399/05/25

**Ethics committee reference number**

IR.ZUMS.REC.1399.191

**Health conditions studied****1****Description of health condition studied**

Schizophrenia

**ICD-10 code**

F20.9

**ICD-10 code description**

Schizophrenia, unspecified

**Primary outcomes****1****Description**

attention of schizophrenic patients

**Timepoint**

In two time periods before starting the drug and 12 weeks after starting the drug

**Method of measurement**

Strop computer test

**2****Description**

executive performance

**Timepoint**

In two time periods before starting the drug and 12 weeks after starting the drug

## Method of measurement

London Tower Computer Test

### 3

#### Description

processing speed

#### Timepoint

In two time periods before starting the drug and 12 weeks after starting the drug

#### Method of measurement

Strop computer test

## Secondary outcomes

### 1

#### Description

negative symptoms

#### Timepoint

In the three time periods before, 8 and 12 weeks after the start of the intervention

#### Method of measurement

Negative Symptoms Assessment Scale

### 2

#### Description

the quality of life

#### Timepoint

Three time periods before, 8 and 12 weeks after the start of the intervention

#### Method of measurement

Specific quality of life questionnaire for schizophrenic patients

## Intervention groups

### 1

#### Description

Intervention group: In addition to the routine treatment of schizophrenia (which includes one of the three antipsychotic drugs: clozapine, risperidone, olanzapine), Sobhan Company Memantine will be prescribed for three months. For this purpose, treatment with 5 mg memantine will be started and 5 mg weekly will be increased to 20 mg, then the 20 mg dose will be continued for two months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In addition to routine treatment, the control group will receive a placebo. Routine treatment that includes one of three antipsychotic drugs: clozapine, risperidone, olanzapine. The follow-up period in the present study is 12 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hakim Maintenance Center

##### Full name of responsible person

Armani Kian Alireza

##### Street address

5 km of Tabriz road (Amadgah road) nursing home for the disabled and the elderly. The first building. Hakim Center

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4537157451

##### Phone

+98 24 3354 1754

##### Fax

##### Email

reyhane.jozghanbari@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Shaghli Alireza

##### Street address

Zanjan University of Medical Sciences.,Professor Yousef Sabouti Boulevard

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

##### Phone

+98 24 3301 8687

##### Email

info@zums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Zanjan 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**  
Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Joz Qanbari Reyhaneh  
**Position**  
resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Shahid Dr. Beheshti Educational, Therapeutic and  
Psychiatric Center., Ark Square  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513615788  
**Phone**  
+98 24 3354 2403  
**Email**  
reyhane.jozghanbari@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Armani kian Alireza  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Deputy of Treatment., third floor., Bustan 2  
.,University of Medical Sciences ., above Ayatollah  
Hospital ., Gavazang Road  
**City**  
Zanjan  
**Province**  
Zanjan

**Postal code**  
4513956111  
**Phone**  
+98 24 3301 8000  
**Email**  
dr.armmami@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Armani kian Alireza  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
third floor., Deputy of Treatment., Bustan  
2.,University of Medical Sciences., above Ayatollah  
Mousavi Hospital.,Gavazang Road  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4513956111  
**Phone**  
098 24 3301 8000  
**Email**  
dr.armmani@gmail.com

## 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

Due to the dissatisfaction of the participants, a decision was made not to publish

### 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