Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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
Cognitive assessment, quality of life and negative symptoms

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)

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+98 24 3301 8149

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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 zanjan University of Medical Sciences

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

City
Zanjan

Province
Zanjan

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
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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
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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

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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