

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effects of Memantine on cognitive impairment in schizophrenic patients

Protocol summary

Study aim

Determining the effect of memantine on cognitive symptoms in patients with schizophrenia

Design

A clinical trial with a placebo group, with parallel groups, blind, randomized, double-blinded

Settings and conduct

This study, which is a randomized, double-blind clinical trial, was conducted on patients aged 50-18 years old with schizophrenia (according to DSM-IV criteria) admitted to Kargrnejad Kashan Psychiatric Hospital for at least 3 months of treatment of schizophrenia were taken.

Participants/Inclusion and exclusion criteria

Patients with schizophrenia according to DSM-IV criteria have a short mental state score of between 18 and 24.

Intervention groups

Patients received 3 to 4 mg anti-cholinergic antibiotics at a constant dose of 300 to 1000 mg of chlorpromazine (with the exception of clozapine) for 3 months and 3 to 8 mg of terrigenophylline. A group treated with memantine was given 5 mg daily for 3 months and received a dose of up to 20 mg daily. This dose was selected according to the effective dose for patients with dementia. The second group was treated with placebo, which was similar in flavor, color and mode, for 3 months. Both groups underwent the usual treatment for schizophrenia (a constant dose of 300-1000 mg of chlorpromazine (excluding clozapine) and a constant dose of anticholinergic drug equivalent to 4 to 8 mg tricyclihphenidyl).

Main outcome variables

Hamilton Depression Scale (HAM-D), Grade Severity of Positive and Negative Symptoms of Schizophrenia (PANSS), Adult Wechsler Memory Score (WAIS-III)

General information

Reason for update

Change the number of samples and start time

Acronym

IRCT registration information

IRCT registration number: **IRCT20190606043827N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **1**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Seyed Ahmad Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5550 0111

Email address

hosseini-sah@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-12-25, 1398/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Memantine on cognitive impairment in schizophrenic patients

Public title

Memantine effect on patients with schizophrenia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Schizophrenia according to DSM-IV criteria Age 18 to 50 years Receiving common drugs for schizophrenia for at least 3 months before the start of the study (Patients within 3 months of the previous 3 month antipsychotic with a constant dose of 300 to 1000 mg of chlorpromazine (except for clozapine) and a fixed dose of anticholinergic drug of 4 to 8 mg TG Phenidyl) Mental Status Mini Test Score (MMSE) Between 18 and 24

Exclusion criteria:

Dependence and drug addiction smoking History of trauma to the head History of seizure Severe liver and kidney function disorders Severe neurological disorders Depression Receiving drugs that affect cognitive symptoms

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients aged 18-50 years with schizophrenia (according to DSM-IV criteria) admitted to Kargarinejad Psychiatric Hospital in Kashan who had been undergoing routine schizophrenia for at least 3 months were randomly selected. Sampling was done randomly until the sample size was completed and information was collected through interviews, observation, and questionnaires. Patients were randomly divided into two groups: A and B. Randomization was done by using a random number table. Regarding concealment, a random sequence was given to a person in this method and sampling was performed at one or more centers simultaneously. Based on the order of the participants' entry into the study, the researcher communicates with the relevant center and asks about the random assignment of the participant to a specific group. Communication methods include phone, SMS, fax, email, and more.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was a double-blind clinical trial. Patients and staff are unaware of the drug and placebo dose.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8711111111

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.kaums.mednt.rec.1398.064

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Adult Wechsler Memory Test Score

Timepoint

Measurement of mean Wechsler Adult Memory Test score from baseline, 6th week and 12th week after drug and placebo study.

Method of measurement

Adult Wechsler memory test

2

Description

Grade Severity of Positive and Negative Symptoms of Schizophrenia

Timepoint

Measure the mean score of severity of positive and negative symptoms of schizophrenia from baseline, 6th week and 12th week after drug and placebo study.

Method of measurement

Questionnaire on the severity of positive and negative symptoms of schizophrenia

3

Description

Hamilton Depression Scale Score

Timepoint

Measurement of mean Hamilton Depression Rating Scale from baseline, 6th and 12th week after drug and placebo study.

Method of measurement

Hamilton Depression Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group was treated with memantine 5 mg (Made in Iran and Tolid daru factory) daily for 3 months and dosed at a maximum of 20 mg daily. This dose was selected according to the effective dose for patients with dementia.

Category

Treatment - Drugs

2

Description

Control group: The second group was treated with placebo, which was similar in flavor, color and mode, for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Psychologist Hospital

Full name of responsible person

Seyed Ahmad Hosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Sadat Qoreysi

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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Seyed Ahmad Hosseini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

In this study, some of the data, such as medical information, can be shared.

When the data will become available and for how long

Start the access period 1 month after printing results

To whom data/document is available

scholars and students

Under which criteria data/document could be used

All scholars and students are required to apply ethical principles to the use of paper data.

From where data/document is obtainable

To the author responsible

What processes are involved for a request to access data/document

Request by email

Comments