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 Kargrinejad 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 tricyclichephenidyl).

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

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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
Isfehan
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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Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan
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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 Qoreyshi
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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
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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