Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Adjunctive Memantine Therapy for Negative Symptoms in Schizophrenia: A Double-Blind Placebo Controlled Study

Protocol summary

Study aim
Effect of memantine on the improvement of cognitive symptoms in schizophrenic patients
Design
Clinical trial with community-based and pragmatic control group, with parallel, double-blind, randomized,
Settings and conduct
Patients were randomly divided into two groups of memantine and placebo recipients (randomized tables). Patients received medication in Avicenna and Hejazi hospitals in Mashhad.
Participants/Inclusion and exclusion criteria
1) Schizophrenia in the relative recovery period 2) aged 18 to 60 years
Intervention groups
In the memantine group, patients started a daily dose of 5 mg memantine, which increased the dose by 5 mg weekly to reach 20 mg / day (in two doses). In the placebo group, the placebo was similar to memantine, according to the same protocol.
Main outcome variables
Changes in psychotic symptoms, cognitive symptoms, extrapyramidal side effects and quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180301038906N1**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **retrospective**

Last update: **2018-06-10, 1397/03/20**
Update count: **0**
Registration date
2018-06-10, 1397/03/20

Registrant information
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Najmeh Shahini
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2015-04-01, 1394/01/12
Expected recruitment end date
2018-05-08, 1397/02/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Adjunctive Memantine Therapy for Negative Symptoms in Schizophrenia: A Double-Blind Placebo Controlled Study

Public title
adding memantine to treatment of schozopherenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Schizophrenia in the relative recovery period Use of atypical antipsychotics including risperidone and olanzapine No other drugs (except anticholinergic and benzodiazepine) Lack of pregnancy or breastfeeding No serious organic disease and no drug use at the time of

entering the study
Exclusion criteria:
There is serious organic disease Pregnancy or breastfeeding Existence of dementia

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Computerized table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, the method of blindness is as follows, and all of the following are blind to intervention. The doctor and the people who take care of the patients A resident who collects data

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Mashhad University of Medical Sciences

Street address
Ibn Sina Hospital

City
mashhad

Province
Razavi Khorasan

Postal code
4915773335

Approval date
2015-03-03, 1393/12/12

Ethics committee reference number
IR.MUMS.fm.REC.1390.11

Health conditions studied

1

Description of health condition studied
schizopherenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
The condition of psychotic symptoms

Timepoint
Week 2,4,6

Method of measurement
wechsler

Secondary outcomes

1

Description
cognitive and negative symptoms

Timepoint
week 2,4,6

Method of measurement
wechsler

Intervention groups

1

Description
Intervention group: For patients, a daily dose of 5 mg of memantine was started, with a dose of 5 mg a week to reach 20 mg / day (in two doses)..Patients in both groups "had an atypical antipsychotic drug, including risperidone and olanzapine.

Category
Treatment - Drugs

2

Description
Control group: For patients, a daily dose of 5 mg of memantine was started, with a dose of 5 mg a week to reach 20 mg / day (in two doses).Patients in both groups "had an atypical antipsychotic drug, including risperidone and olanzapine.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ibn Sina Hospital

Full name of responsible person
raheleh jahantigh

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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences
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Raheleh Jahantigh
Position
Psychiatrist
Latest degree
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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