

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

Name

Najmeh Shahini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3215 5653

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shahinin921@mums.ac.ir

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 schizophрения

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

schizophrenia

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

Street address

hore ameli

City

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pr.mohammadreza.fayyazi@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

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Email

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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

Full name of responsible person

Raheleh Jahantigh

Position

Psychiatrist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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