

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Oct 2026

The effect of memantine with a dose of 20 mg for the treatment of obsessions in bipolar patients with a fixed regimen of quetiapine and lithium

Protocol summary

Study aim

The effect of memantine with a dose of 20 mg for the treatment of obsessions in bipolar patients with a fixed regimen of quetiapine and lithium

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 46 patients.

Settings and conduct

It is performed in a double-blind manner in the psychiatry department of Golestan Hospital, Ahvaz. Bipolar patients are divided into two groups of 23 people and treated with 10 mg of memantine. Placebos are assigned to the control group, and after six weeks, the effects and side effects are checked in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 18-65, bipolar patients with obsessive-compulsive comorbidity, and consent of the patient.

Intervention groups

Intervention group: In addition to the routine bipolar treatment, 10 mg (Shefa Daroo Company) memantine tablets as one tablet after a detailed history and confirmation of the patient's obsession. Control group: In addition to the routine treatment of the bipolar disorder, they will receive a placebo tablet that is similar to memantine in terms of shape, smell, taste, size and colour and is prepared by the Faculty of Pharmacy of Ahvaz University in the same way as the intervention group.

Main outcome variables

Obsession score, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240601061976N1**

Registration date: **2024-06-05, 1403/03/16**

Registration timing: **prospective**

Last update: **2024-06-05, 1403/03/16**

Update count: **0**

Registration date

2024-06-05, 1403/03/16

Registrant information

Name

Hamzeh Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 0000

Email address

rostami_h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of memantine with a dose of 20 mg for the treatment of obsessions in bipolar patients with a fixed regimen of quetiapine and lithium

Public title

Investigating the effect of memantine for the treatment of obsessions in bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18-65 Bipolar patients with obsessive compulsive comorbidity Consent of the patient's guardian

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) generates a random list based on the desired sample size and block size of 4. After creating a list, each patient will be identified with a unique code throughout the study. 23 patients are selected for the intervention group and 23 for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, the researcher, and the treatment staff are kept blind, and the drugs are adjusted by a nurse not related to the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address

Golestan St., Esfand St., Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2024-01-06, 1402/10/16

Ethics committee reference number

IR.AJUMS.REC.1402.527

Health conditions studied

1

Description of health condition studied

Bipolar

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Obsession score

Timepoint

Before the intervention, 3, and 6 weeks after the intervention

Method of measurement

According to DSM-5 criteria

2

Description

Side effects of memantine

Timepoint

During the study, 3, and 6 weeks after the intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine bipolar treatment, 10 mg (Shafa Company) Memantine tablets as one tablet after a detailed history and confirmation of the patient's obsession.

Category

Treatment - Drugs

2

Description

Control group: In addition to the routine bipolar treatment, placebo tablets, which are similar to memantine tablets in terms of shape, smell, taste, size, and color, and are prepared by the Faculty of Pharmacy of Ahvaz University, are received in the same way as the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatry Department of Golestan Hospital

Full name of responsible person

Hamzeh Rostami

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Golestan St., Esfand St., Ahvaz Jundishapur University of Medical Sciences

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Rostami_h@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hamzeh Rostami

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

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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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Hamzeh Rostami
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Latest degree
Specialist
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable