

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of memantine on the symptoms of Borderline personality disorder in the Iranian population

Protocol summary

Study aim

The effect of Memantine on the symptoms of Borderline personality disorder

Design

A clinical trial with a control group, double-blinded, randomized, phase 3 on 40 patients

Settings and conduct

Forty people with BPD are selected and given placebo or memantine orally, depending on which group they belong to. Patient selection and psychological evaluations as well as blood sampling are performed in Iran Psychiatric Hospital. The researcher does not know whether the patient being evaluated belongs to the placebo group or the memantine group. The patients also do not know if they have used placebo or memantine. Drugs and placebos are similar in appearance, such as color, shape, and so on. The patient (placebo or treatment groups) receives the drug in encoded packets. The coding is done by the psychiatrist and the evaluator and the patient are blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women or men between the ages of 16 and 45 who have been diagnosed with BPD using The Best. Exclusion criteria: Clinical evidence of neurological disorders Pregnancy or breastfeeding

Intervention groups

40 selected patients are divided into two groups of treatment and control (n = 20) The treatment group takes 10 mg for the first week, followed by a daily administration of 20 mg of memantine up to the end of week four. The control group receives a placebo daily during this period.

Main outcome variables

symptoms of the disease; Serum levels of memantine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210106049948N1**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Fariba Karimzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5003

Email address

karimzade.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of memantine on the symptoms of Borderline personality disorder in the Iranian population

Public title

Memantine and borderline personality disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women or men between the ages of 16 and 45 who have been diagnosed with BPD using the BEST tool for the disease.
Exclusion criteria:
 Clinical evidence of any pathology in the central nervous system, neurological disorders, head injuries, epilepsy or history of seizures Pregnancy or breastfeeding Taking medications that may interact with memantine

Age
From **16 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Following patients' examinations in the Iran Psychiatric Hospital and reviewing the inclusion criteria and eliminating patients who have exclusion criteria, they are divided into two groups by simple randomization, and a code was specified to every patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher does not know whether the patient being evaluated belongs to the placebo group or the memantine group. The patients also do not know if they have used placebo or memantine. Drugs and placebos are similar in appearance, such as color, shape, and so on. The patient (placebo or treatment groups) receives the drug in encoded packets. The coding is done by the psychiatrist and the evaluator and the patient are blind.

Placebo
Used

Assignment
Other

Other design features
There are no unique specifications.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address
 Cellular and Molecular Research Center, Iran
 University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
14665-354

Approval date
2021-02-03, 1399/11/15

Ethics committee reference number
IR.IUMS.REC.1399.1185

Health conditions studied

1

Description of health condition studied

Borderline personality disorder

ICD-10 code

F60.3

ICD-10 code description

Borderline personality disorder

Primary outcomes

1

Description

Serum levels of memantine

Timepoint

Measurement of serum levels of memantine at the beginning of the study (before the intervention) and at the end of the treatment period

Method of measurement

High Performance Liquid Chromatography

2

Description

Symptoms

Timepoint

beginning of the study (before the intervention) and At the end of weeks 2, 4, 6 and 8

Method of measurement

The Best test

Secondary outcomes

1

Description

Number of suicides

Timepoint

At the beginning of the study (before the intervention) and at the end of the intervention

Method of measurement

interview with patients

Intervention groups

1

Description

The placebo group will receive a placebo for 12 weeks. At the end of weeks 2, 4, 6, and 8, BPD symptoms will be evaluated by the Best test. Blood samples will be gathered before the intervention and at the end of the treatment period. Patients take a placebo daily which is made in Iran.

Category

Placebo

2

Description

The treatment group will receive a placebo for 8 weeks. The patients will take 10 mg Memantine daily in week 9. followed by 20 mg Memantine daily from week 10 to 12. At the end of weeks 2, 4, 6, and 8, BPD symptoms will be evaluated by the Best test. Blood samples will be gathered before the intervention and at the end of the treatment period. Memantine is made in Tasnim Darou Company in Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Fariba Karimzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fariba Karimzadeh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Position
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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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