Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 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)

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+98 21 8670 5003

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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 Chromatograpy

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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Cellular and Molecular Research Center, Iran University of Medical Sciences, Hemmat Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fariba Karimzadeh
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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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Fariba Karimzadeh

Position
Assistant professor

Latest degree
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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