Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Investigating the effect of adding memantine to current therapies on the symptoms of post-traumatic stress disorder

Protocol summary

Study aim
Investigating the effect of adding memantine to current therapies on the symptoms of post-traumatic stress disorder

Design
A randomized double-blind randomized controlled clinical trial is performed on 30 patients. Random blocking will be used for randomization.

Settings and conduct
In this study, patients referred to the psychiatric clinic of Khorshid Hospital in Isfahan are selected as double random blocks. Clinical interviews are performed by a psychiatrist before treatment, 8 weeks later, and 16 weeks later. The CAPS questionnaire is assessed before treatment, 8 weeks later, and 16 weeks later. Patients are then examined in two groups together at different times.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Male and female patients with an age range of 19 to 65 years 2. A case of PTSD resulting from a battle scene that was diagnosed at least 12 months ago according to DSM criteria 5 Exclusion Criteria : 1. Patients with a history of dementia, schizophrenia, bipolar disorder, anxiety disorders, traumatic brain injury, and seizures according to DSM 5 criteria 2. Patients with a history of alcohol and psychotropic drug use in a recent month or the presence of addiction in the patient's history 3. Patients in need of treatment with drugs affecting the glutamatergic system such as amantadine, dexamethasone or carbonic anhydrase inhibitors

Intervention groups
Patients in the first group or intervention group, in addition to the current treatment, are treated with the drug memantine with a starting dose of 5 mg per day and then increase the dose of the drug by 5 mg per week to a maximum dose of 20 mg per day. The patients of the second group, in addition to the current treatment, are treated with a placebo, which is provided by a pharmaceutical company in Isfahan University of Medical Sciences.

Main outcome variables
Symptoms of post-traumatic stress disorder

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200923048816N1**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-13, 1399/07/22**
Update count: **0**

Registration date
2020-10-13, 1399/07/22

Registrant information

Name
Fatemeh Fozveh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3786 1563

Email address
drfozveh.f@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-11, 1399/06/21

Expected recruitment end date
2020-12-05, 1399/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of adding memantine to current therapies on the symptoms of post-traumatic stress disorder

Public title
Investigating the effect of adding memantine to current therapies on the symptoms of post-traumatic stress disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male and female patients with an age range of 19 to 65 years A case of battlefield PTSD diagnosed at least 12 months in advance according to DSM 5 criteria
Exclusion criteria:
Patients with a history of dementia, schizophrenia, bipolar disorder, anxiety disorders, traumatic brain injury, and seizures according to DSM 5 criteria Patients with a history of alcohol and psychotropic drug use in the last month or the presence of addiction in the patient's history Patients need treatment with drugs that affect the glutamatergic system such as amantadine, dexamethasone or carbonic anhydrase inhibitors
Age
From **19 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

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

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients referred to a psychiatric clinic who meet the inclusion criteria are selected as double random blocks. The epidemiologist sets up a random number table, according to which the codes are assigned by hiding the code card in the thick envelopes (Concealed allocation), one of them to the memantine group with current treatment and the other to the placebo group with current treatment. Randomly assigned. These random double blocks continue until the data collection period is complete.
Blinding (investigator's opinion)
Double blinded
Blinding description
To prevent bias and maintain blindness of the drugs in the intervention group and placebo, the patient prescribing the drug, the evaluator and the statistical consultant do not know the type of drug. Patients are treated up to 16 weeks after the intervention and re-examined at weeks 8 and 16. The psychiatrist who visits the patient and gives the packaged and coded drugs to the patient, the researcher who fills out the questionnaire, the researcher who enters the data into the software, and the epidemiologist who analyzes, the blind people in study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Unit 2, Building 33, Shahid Alikhani Alley, Shahid Karimian Alley, Bagh Lake Street.
City
Isfahan
Province
Isfehan
Postal code
2248795031
Approval date
2020-09-23, 1399/07/02
Ethics committee reference number
IR.MUI.MED.REC.1399.527

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Symptoms of post-traumatic stress disorder
Timepoint
At the beginning of the study, the eighth week and the sixteenth week
Method of measurement

Clinical Administered PTSD Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Current treatment with memantine Patients in the first group or intervention group, in addition to the current treatment, are treated with the drug memantine with a starting dose of 5 mg per day and then increase the dose of the drug by 5 mg per week to a maximum dose of 20 mg per day.
Category
Treatment - Drugs

2

Description
Control group: Current treatment with placebo
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric clinics affiliated to Isfahan University of Medical Sciences
Full name of responsible person
Fatemeh Rajabi
Street address
No. 13, Mousavi Crossroads, Foroughi St., Shohada Square.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fakhri Sadat Khalifa Soltani
Street address
Unit 2, Building 33, Shahid Alikhani Alley, Shahid Karimian Alley, Bagh Lake Street.
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Phone
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bsrc@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Fozveh
Position
Psychiatric resident
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)
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
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