

# 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**

Isfahan

**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**

## 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.

##### City

Isfahan

##### Province

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##### Postal code

3466878945

##### Phone

+98 31 3338 6010

##### Email

bsrc@mui.ac.ir

## 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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##### Postal code

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##### Phone

+98 31 3786 1563

##### Email

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

Medical doctor

##### Other areas of specialty/work

Psychiatrics

##### Street address

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

**Full name of responsible person**

Fatemeh Fozveh

**Position**

Psychiatric resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

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**Latest degree**

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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