

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation of prophylactic effect of memantine in comparison with placebo on post-traumatic headache in patients with head trauma 3 months and 6 months after starting the drug

#### Protocol summary

##### Study aim

Evaluation of prophylactic effect of memantine in comparison with placebo on post-traumatic headache in patients with head trauma 3 months and 6 months after starting the drug

##### Design

Clinical trial with control group, with single groups, double-blind, randomized, phase 3 on 90 patients. Patients are assigned to the treatment and control groups in double random blocks in such a way that patients are identified in pairs and both people who are placed in a block are randomly assigned to one person in the treatment group and another person in the control group. Are placed until the sample size is complete.

##### Settings and conduct

A double-blind randomized clinical trial (patient and researcher) in Al-Zahra Hospital in Isfahan. Memantine is prescribed for the intervention group and placebo for the control group for up to three months.

##### Participants/Inclusion and exclusion criteria

Participants are people over the age of 18 who have head trauma and are fully satisfied to enter the study. Conditions of non-entry include a history of severe neurological disease, a history of severe mental disease, and brain complications due to trauma such as infections.

##### Intervention groups

For patients in the intervention group, memantine tablets are prescribed for three months, and placebo is prescribed for patients in the control group. The pharmaceutical company of the patients' pills is the same.

##### Main outcome variables

Pain in patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201005048944N1**

Registration date: **2021-01-11, 1399/10/22**

Registration timing: **retrospective**

Last update: **2021-01-11, 1399/10/22**

Update count: **0**

##### Registration date

2021-01-11, 1399/10/22

##### Registrant information

##### Name

Elham Bani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3620 2020

##### Email address

bani@resident.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2020-09-05, 1399/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of prophylactic effect of memantine in comparison with placebo on post-traumatic headache in patients with head trauma 3 months and 6 months after starting the drug

## Public title

Evaluation of the effect of memantine for the prevention of headaches caused by head trauma

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

People who have head trauma

### Exclusion criteria:

Having a history of severe neurological disease Having a history of severe mental illness Having brain complications from trauma such as infections

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In order to prepare placebo and memantine (main drug), we refer to the School of Pharmacy and they provide for us two similar drug packages with the same shape without informing the researcher and the patient. After conducting the research, during the data analysis, the type of drug (placebo or memantine ) is decoded by the pharmaceutical company (Hakim).

## Placebo

Used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan university of Medical sciences

##### Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۸۱۳۷۸۶۶۵۱۵

##### Approval date

2020-05-08, 1399/02/19

##### Ethics committee reference number

IR.MUI.MED.REC.1399.124

## Health conditions studied

### 1

#### Description of health condition studied

post traumatic headache

#### ICD-10 code

G44.3

#### ICD-10 code description

post traumatic headache

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

3 months and 6 months after treatment

#### Method of measurement

Visual Analogue Scale questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Memantine tablets are an N-methyl-D-aspartate (NMDA) receptor-dependent inhibitor of the glutamate receptor subtype. For patients in the intervention group, 10 mg of memantine tablets are prescribed for half a tablet a day for two weeks and then one tablet a day for 5 months. The manufacturer is Hakim Pharmaceutical Company.

#### Category

Prevention

## 2

### Description

Control group: A placebo is prescribed for patients in the control group.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Al-Zahra Hospital, Isfahan

**Full name of responsible person**

elham bani

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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alzahra@mui.ac.ir

**Web page address**

<http://alzahra.mui.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

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<http://med.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**

elham bani

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

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School of Medicine, Isfahan University of Medical Sciences and Health Services, Hezar Jarib St

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

fariborz khorvash

**Position**

full Profesor

**Latest degree**

Subspecialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Elham Bani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Department of Neurology, Alzahra Hospital, Softe Blvd

**City**

Isfahan

**Province**

## 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