Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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

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Isfahan

Province
Isfehan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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elham bani
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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