

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of Memantine on migraine pain severity, mental health and quality of life in patients with migraine

#### Protocol summary

##### Study aim

The effect of Memantine on migraine pain severity, mental health and quality of life in patients with migraine.

##### Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 84 patients. SPSS software was used for randomization.

##### Settings and conduct

This study was performed on 84 patients with migraine in Isfahan. The subjects were selected from among the patients referred to the neurology clinics of Imam Musa Sadr Clinic and Khorshid Hospital with the diagnosis of a neurologist. Topiramate With dosage 50 mg daily and in the intervention group, in addition to topiramate, memantine is used at a dose of 10 mg daily for two months as prophylaxis. To assess the quality of life and mental health of patients, questionnaires (Headache Impact Test: HIT And PHQ: Patient Health Question) and Visual Analogue Scale (VAS) is completed by patients before and two months after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient satisfaction Having a migraine criterion based on the International Headache Association criteria Exclusion criteria: History of addiction to any drug Treated with herbal medicines and other palliative medicine treatments Treated with other prophylactic drugs Concomitant treatment with corticosteroids

##### Intervention groups

For the intervention group, memantine at a dose of 10 mg daily for two months is used as prophylaxis. Also, in both groups (control group and memantine receiving group), topiramate with dosage 50 mg daily is used prophylactically for two months. Topiramate was used once a night in this study, but the patient is responsible for the time of taking memantine and the specific time of day and night has no effect on its effect.

##### Main outcome variables

Pain severity; mental health; Quality of Life; Number of headaches; The duration of the headache.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171230038142N21**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **retrospective**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

##### Registration date

2020-09-21, 1399/06/31

##### Registrant information

##### Name

Khosro Tavakol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 9134

##### Email address

tavakol@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-21, 1398/05/30

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

2019-08-21, 1398/05/30

##### Actual recruitment end date

2020-05-11, 1399/02/22

**Trial completion date**

2020-08-20, 1399/05/30

**Scientific title**

The effect of Memantine on migraine pain severity, mental health and quality of life in patients with migraine

**Public title**

The effect of Memantine in migraine patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient satisfaction Having a migraine criterion based on the International Headache Association criteria

**Exclusion criteria:**

History of addiction to any drug Treated with herbal medicines and other palliative medicine treatments Treated with other prophylactic drugs Treated with corticosteroids

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **84**

Actual sample size reached: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling is non-probabilistic and sequential. In this way, all patients who are eligible to enter the study, enter the study until the sample size is completed. Then, using SPSS computer software, they are randomly assigned to two groups of control and intervention.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jarib Ave., Isfahan University of Medical Sciences.

**City**

Isfahan

**Province**

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**Postal code**

81746-73461

**Approval date**

2019-07-16, 1398/04/25

**Ethics committee reference number**

IR.MUI.MED.REC.1398.201

**Health conditions studied****1****Description of health condition studied**

Migraine

**ICD-10 code**

G43

**ICD-10 code description**

Migraine

**Primary outcomes****1****Description**

Quality of life

**Timepoint**

Before and two months after the start of the intervention

**Method of measurement**

Headache Impact Test: HIT

**2****Description**

Mental Health

**Timepoint**

Before and two months after the start of the intervention

**Method of measurement**

Patient Health Questionnaire: PHQ

**3****Description**

Severity of headache

**Timepoint**

Before and two months after the start of the intervention

**Method of measurement**

Visual Analogue Scale

**4****Description**

Duration of headache per attack

**Timepoint**

Before and two months after the start of the intervention

**Method of measurement**

Question from the patient

## 5

### Description

Number of headaches per week

### Timepoint

Before and two months after the start of the intervention

### Method of measurement

Question from the patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: In this group, there are 42 patients with migraine who use topiramate at a dose of 50 mg made by Sobhan Iranian Pharmaceutical Company. This drug is used daily for two months as a prophylaxis. Topiramate is used once a night in this study.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: For the intervention group, memantine at a dose of 10 mg daily for two months is used as prophylaxis. Also, topiramate at a dose of 50 mg daily for two months is used as prophylaxis. Topiramate was used once a night in this study, but the patient is responsible for the time of taking memantine and the specific time of day and night has no effect on its effect.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Khorshid Hospital

##### Full name of responsible person

Fariborz Khorvash

##### Street address

Ostandari Street.

##### City

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##### Phone

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## 2

#### Recruitment center

##### Name of recruitment center

Imam Musa Sadr Clinic

##### Full name of responsible person

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Mousavi crossroads, Foroughi street, 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

Shaghayegh Haghjooye Javanmard

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Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib St.

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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  
**Full name of responsible person**  
Fariborz Khorvash  
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Associate Professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data are available two years after the results are published after the patients are anonymous.

### When the data will become available and for how long

Two years after the results are published

### To whom data/document is available

Physicians and neurologists

### Under which criteria data/document could be used

Compare new drug or new dose with existing information

### From where data/document is obtainable

Send email to Fkhorvash@gmail.com

### What processes are involved for a request to access data/document

Send email to Fkhorvash@gmail.com

### Comments