

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

Isfahan

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

Isfahan

Province

Isfahan

Postal code

81746-73558

Phone

+98 31 3222 2127

Email

Fkhorvash@gmail.com

2

Recruitment center

Name of recruitment center

Imam Musa Sadr Clinic

Full name of responsible person

Fariborz Khorvash

Street address

Mousavi crossroads, Foroughi street, Shohada square.

City

Isfahan

Province

Isfahan

Postal code

81746-44123

Phone

+98 31 3338 6010

Email

Fkhorvash@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooye Javanmard

Street address

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

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3668 5149

Email

sh_haghjoo@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
Fariborz Khorvash
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Ostandari Street
City
Esfahan
Province
Isfahan
Postal code
81746-73558
Phone
+98 31 3668 0048
Email
Fkhorvash@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fariborz Khorvash
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Ostandari st.
City
Isfahan
Province
Isfahan
Postal code
81746-73558
Phone
+98 31 3668 0048
Email
Fkhorvash@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Neda Abrishami
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Biostatistics
Street address
Isfahan University of Medical Sciences, Hazar Jarib Street
City
Esfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 8597
Fax
Email
dadepardaz2005@gmail.com

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