

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effectiveness of adding Memantine to Topiramate in the prevention of headache attacks among patients with chronic migraine headaches

Protocol summary

Study aim

The aim of this study is to evaluate the effect of Memantine on decreasing frequency, severity and duration of headaches in patients with chronic migraine.

Design

This study will be done on a double blind randomized controlled clinical trial on 54 patients aged 18-65 years old with chronic migraine headache referring to neurology clinic of Hospitals in Ahvaz city.

Settings and conduct

This study was done on patients referring to Neurology clinic of Hospitals in Ahvaz city. Patients were divided into two equal groups of intervention and control (number = 27) by block randomization and they had no awareness of grouping way. Pain severity, disability level and frequency of attacks at the beginning of study, at first, second, third, and fourth month were recorded in follow-ups. The severity of headache was measured using the visual analog scale and the disability level was measured using the Migraine Disability Assessment Test Survey.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 to 65 years old; Chronic migraine headache according to International Classification of headache. Exclusion Criteria: Pregnancy or breast-feeding; Renal or hepatic impairment or known cardiovascular disease; History of allergy to memantine and topiramate.

Intervention groups

Intervention group: receiving Memantine and Topiramate
Control group: receiving Placebo and Topiramate

Main outcome variables

Severity of migraine headache attacks; Disability level of migraine headache attacks; Frequency of migraine headache attacks; Duration of migraine headache attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191205045623N1**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **retrospective**

Last update: **2019-12-26, 1398/10/05**

Update count: **0**

Registration date

2019-12-26, 1398/10/05

Registrant information

Name

Sahereh Emadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

sahere.emadi.64@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-20, 1396/01/31

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

2017-04-20, 1396/01/31

Actual recruitment end date

2017-11-18, 1396/08/27

Trial completion date

2018-03-19, 1396/12/28

Scientific title

The effectiveness of adding Memantine to Topiramate in the prevention of headache attacks among patients with chronic migraine headaches

Public title

Prophylactic Effect of Memantine on Chronic Migraine Headache

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 65 years old Chronic migraine headache according to International Classification of headache

Exclusion criteria:

Pregnancy or breast-feeding Renal or hepatic impairment or known cardiovascular disease History of allergy to memantine and topiramate

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method was used for randomization. Nine blocks were created by www.randomizer.org. The blocks were the same size and equal to 6. In each block, there were three allocations for the intervention group and three allocations for the control one. In each block, 1 and 2 numbers were given in different order, which determined the group of patients. Number one was considered as intervention group and number two was used as control group. Patients were randomly assigned to intervention or control groups after diagnosis of chronic migraine on the basis of one and two numbers in blocks. Also the random sequence of blocks was in the hands of an individual other than the researcher who, by telephone, provided only the required number indicating the intervention or control group. Without researchers intervention, the patients were assigned to each groups based on numbers. After sampling accomplished, each groups had the same size with number of 27.

Blinding (investigator's opinion)

Double blinded

Blinding description

None of the patients in this study knew that they were in the intervention or control group and that the treatment received was either drug or placebo. Also, none of the researchers had a direct role in the process of grouping and follow up of patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Development Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan Blvd, Ahvaz

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Ahvaz

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Khuzestan

Postal code

6135715794

Approval date

2017-04-20, 1396/01/31

Ethics committee reference number

IR.AJUMS.REC.1396.630

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

Migraine headache

ICD-10 code

G43

ICD-10 code description

Migraine

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

The severity of migraine headache attacks

Timepoint

This evaluation was performed at the beginning of the study, and the end of first, second, third and fourth months of the study.

Method of measurement

Visual Analogue Scale

2**Description**

The disability level of migraine headache attacks

Timepoint

This evaluation was performed at the beginning of the study, and the end of first, second, third and fourth months of the study.

Method of measurement

Migraine Disability Assessment Test Survey (MIDAS)

3

Description

The frequency of migraine headache attacks

Timepoint

This evaluation was performed at the beginning of the study, and the end of first, second, third and fourth months of the study.

Method of measurement

Daily headache diary

4

Description

The duration of migraine headache attacks

Timepoint

This evaluation was performed at the beginning of the study, and the end of first, second, third and fourth months of the study.

Method of measurement

Daily headache diary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in intervention group received Memantine tablet 20 mg daily which reached this level after 4 weeks and they received topiramate tablet 50 mg daily as a base medication which started at 25 mg daily and increased to 50 mg daily in two weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients in control group received placebo that it was similar to memantine tablet in shape and color and they received topiramate tablet 50 mg daily as a base medication which started at 25 mg daily and increased to 50 mg daily in two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Sahereh Emadi

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

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Web page address

<http://vchresearch.ajums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Davood Kashipazha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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