Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 refereeing to neurology clinic of Hospitals in Ahvaz city.

Settings and conduct
This study was done on patients refereeing 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 awarness 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 Memantin 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)
Phone
+98 61 3374 3012
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 accomplisehed, 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, Ahwaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
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
Street address
Clinic of Neurology, Golestan Hospital, Farvardin St., Golestan, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3012
Email
sahere.emadi.64@gmail.com

2

Recruitment center
Name of recruitment center
Imam khomeyni Hospital
Full name of responsible person
Sahereh Emadi
Street address
Clinic of neurology, Imam khomeyni Hospital, Azadegan St.
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2818
Email
sahere.emadi.64@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Development Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Esfand Avenue, Golestan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3336 2414
Fax
+98 61 3336 1544
Email
itc@ajums.ac.ir
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

Neurology

Street address

Department of Neurology, Golestan Hospital, Farvardin St., Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3012

Email

dakashi47@gmail.com

Person responsible for scientific 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

Neurology

Street address

Department of Neurology, Golestan Hospital, Farvardin St., Golestan

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Postal code

6135733118

Phone

+98 61 3374 3012

Email

dakashi47@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sahereh Emadi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Department of Neurology, Golestan Hospital, Farvardin St., Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3012

Fax

Email

sahere.emadi.64@gmail.com

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