Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effects of memantine and sodium valproate in migraine pain prophylaxis

Protocol summary

Study aim
Comparison the effects of memantine and sodium valproate in migraine pain prophylaxis

Design
The clinical trial in phase 3 has two groups, community-based with parallel groups, double-blind and pseudo randomization methods

Settings and conduct
Migraine patients referring to neurology clinics of Ardabil University of Medical Sciences will be reviewed. This study will be done as double-blinded form (blindness of patients, researcher and physicians). Patients will be divided into two groups of 40 by pseudo randomization method. We will use Memantine for a group and sodium valproate for another group for 12 weeks. After taking their medications, patients do not receive any medication for 4 weeks.Then we will give memantine to sodium valproate group and sodium valproate to memantine group for another 12 weeks. Patients will be visited every four weeks by their neurologist according to a pre-prepared questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Migraine history, more than 3 headache attacks per month, prophylactic treatment failure with one or more migraine prevention drugs, aged 16 to 65 years, spacing more than 48 hours between attacks Exclusion criteria: Other headaches, use of other migraine prevention medications, drug dependence on drugs or alcohol, renal failure, excessive use of acute migraine attack drugs

Intervention groups
Group 1: These patients will receive 10mg of memantine coated tablets per day and will be continued for 12 weeks. Group 2: These patients will receive 400mg of sodium valproate coated tablets daily and will continue for 12 weeks. Then patients will not take any drug for 4 weeks and then will be given sodium valproate to patients in group 1 and memantine to patients in group 2 for 12 weeks

Main outcome variables
Headache score by MIDAS score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180624040229N1**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **retrospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date
2019-01-02, 1397/10/12

Registrant information

Name
Rogayye Dargahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3323 0739

Email address
arumail@arums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-10-12, 1397/07/20

Actual recruitment start date
2018-01-21, 1396/11/01

Actual recruitment end date
2018-10-12, 1397/07/20

Trial completion date
2018-10-12, 1397/07/20

Scientific title
Comparison the effects of memantine and sodium valproate in migraine pain prophylaxis

Public title
Comparison the effects of memantine and sodium valproate in migraine pain prophylaxis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
A history of migraines based on the criteria of the international community of headache. The number of headache attacks is more than three attacks per month. Failure of prophylactic treatment with one or more migraine prevention drugs. Any headache attack with more than 48 hours of analgesia should be distinguished from other attacks Filling out the consent form of the Clinical trial age 16 to 65

Exclusion criteria:
Other headache Use of other migraine prevention medications Drug dependence on drugs or alcohol Renal dysfunction Excessive use of acute migraine attack drugs (more than 8 days in the month of receiving ergots, NSAIDs or tryptans) Sensitization to memantine or sodium valproate or their compounds. Acute resistant migraine Severe psychiatric disorders (bipolar disorder, mental disorder, severe depressive disorder, obsessive-compulsive disorder, or functional disorder, general anxiety disorder, Somatization) Neurodegenerative disorders malignancy , pain disorder, severe infection Pregnant or Breastfeeding women

Age
From **16 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The way of participant blindness is that he will receive and use a certain number of drugs in an unnamed and labeled envelope. The way of physicians blindness is that after he has been diagnosed migraine to his patient and notice his secretary, randomly given one of the envelopes to the patient. The way of researcher's blindness is that he will not be present in the filling envelopes and selecting them.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences

Street address
No. 1, Moallem street,

City
Ardabil

Province
Ardabil

Postal code
5613843793

Approval date
2017-10-23, 1396/08/01

Ethics committee reference number
IR.ARUMS.REC.1396.80

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura

Primary outcomes

1

Description
Headache score by MIDAS score

Timepoint
At the beginning , 3 month later, 6 month later

Method of measurement
MIDAS score

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Memantine, 5 mg oral tablet (Sobhan company), twice a day for 12 weeks. Then 4 weeks without taking any medication. Then take 200 mg of sodium valproate (Raha company), twice a day for 12 weeks
Category
Treatment - Drugs

2

Description
Second Intervention group: Sodium valproate, 200 mg oral tablet (Raha company), twice a day for 12 weeks. Then 4 weeks without taking any medication. Then take 5 mg of Memantine (Sobhan company), twice a day for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Hospital
Full name of responsible person
Meysam Fouladi
Street address
Royan clinic, Pasdaran St
City
Ardabil
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5613843793
Phone
+98 45 3323 0739
Email
Reseteam.2020@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
Street address
Ardabil university of medical sciences, Daneshgah St
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5618985991
Phone
+98 45 3352 2247
Email
info@arums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Vahid Abbasi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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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
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After unidentified people, demographic data and MIDAS score will be used to evaluate the headache.
When the data will become available and for how long
Starting the access from 2020
To whom data/document is available
Access will be free for everyone
Under which criteria data/document could be used
Statistical analyzes are allowed on data
From where data/document is obtainable
Will be contact by Dr Abbasi`s email
What processes are involved for a request to access data/document
It takes a total of one month
Comments
No other information is required