Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Memantine versus Valproate in episodic migraine; a double blind randomized controlled trial

Protocol summary

Summary

This is a double blind, Randomized Clinical Trial (RCT) that patients diagnosed with migraine (men and women within an age range of 18-65), according to IHS diagnostic criteria, with more than 6 attacks per month and taking no migraine prophylaxis medications, after obtaining informed consent, and explain the possible side effects of medication are included in randomized blocks under treatment with Memantine, 10mg per day, or Sodium Valporate (Depakine), 500mg per day, and are investigated 3 months after medication. Neither the patients nor the physicians are aware of the type of medication used in each group. The primary outcome measure is the average number of attacks in each month. Secondary outcome measures are: Average number of days with migraine headaches per month, The mean pain intensity from 0-3 before taking an analgesic, Number and type of medications used per attack, Number of respondents (50% or more reduction in rate of attacks, 50% or more reduction in the number of days with migraine headaches), Side effects and Quality of life. SF-12, MIDAS and HADS is filled at the beginning and the end of the study for evaluating patients' performance. In the case of no improvement in patient's headache or Exacerbation of it , standard migraine prophylaxis medication will be applied and at the end it will be decoded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112611424N2**
Registration date: **2015-10-08, 1394/07/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-08, 1394/07/16

Registrant information

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Abbas Tafakhori
Name of organization / entity
Iranian Center of Neurological Research
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Memantine versus Valproate in episodic migraine; a double blind randomized controlled trial

Public title

Memantine versus Valproate in episodic migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Men and women diagnosed with migraine within an age range of 18-65 and the onset of

disease before their 50s; The duration of migraine is at least 1 year; at least 6 attacks per month; at least 48 hours without headache between 2 attacks; no migraine prophylaxis until inclusion Exclusion criteria:Renal dysfunction; Having ICDH-II criteria for medication overuse headache; Taking antipsychotics or antidepressants in last 3 months; Drug or alcohol abuse; Allergic reactions to memantine and Its compounds; Resistance to all acute migraine medications; Pain disorders; severe psychiatric disorder; Severe infections; Malignancy; Low chance of survival; Severe cardiac and vascular diseases; Neurodegenerative diseases; Pregnancy and lactation; Women in childbearing age and sexually active are included in the study, only if they receive contraception; MIDAS greater than 18

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Qods Street, Keshavarz blv.

City
Tehran

Postal code

Approval date
2015-09-01, 1394/06/10

Ethics committee reference number
IR.TUMS.REC.1394.131761

Health conditions studied

1

Description of health condition studied
Migraine without aura

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
The average number of attacks in each month

Timepoint
3 months of retrospective history taking before intervention, 1 month of prospective history taking before intervention, 3 months after onset of intervention

Method of measurement
Migraine diary

Secondary outcomes

1

Description
Anxiety

Timepoint
at baseline,3 months after intervention

Method of measurement
Hospital anxiety and depression scale

2

Description
Number and type of medications used per attack

Timepoint
at baseline,3 months after intervention

Method of measurement
Migraine diary

3

Description
Functional disability

Timepoint
at baseline,3 months after intervention

Method of measurement
Migraine Disability Assessment (MIDAS)

4

Description
Side effects

Timepoint
at baseline,3 months after intervention

Method of measurement
Migraine diary

5

Description
The mean pain intensity from 0-3 before taking analgesic
Timepoint
at baseline,3 months after intervention
Method of measurement
Migraine diary

6

Description
Average number of days with migraine headaches per month
Timepoint
at baseline,3 months after intervention
Method of measurement
Migraine diary

7

Description
Quality of life
Timepoint
at baseline,3 months after intervention
Method of measurement
SF-12

8

Description
Number of respondents
Timepoint
at baseline,3 months after intervention
Method of measurement
Migraine diary

9

Description
Depression
Timepoint
at baseline,3 months after intervention
Method of measurement
Hospital anxiety and depression scale

Intervention groups

1

Description
Intervention: The first group will be treated with Memantine (10 mg daily, orally) for 3 months.
Category
Treatment - Drugs

2

Description
Control: In this group, patients will be treated with Sodium Valporate (Depakine), 500 mg per day, orally, for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Abbas Tafakhori
Street address
Imam Khomeini Hospital, End of Keshavarz Blvd., Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Masood Yunesian
Street address
Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Position
MD, Neurologist
Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty