Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

pelacebo controlled trial to double blind randomised evaluate memantine efficacy in Migraine without aura patients referred to Imam Khomeini hospital

Protocol summary

Summary

Migraine is one of the most common neurologic disorders.It usually shows up with pulsating headache, aura, nausea, vomit, photophobia, or phonophobia. Migraine pathophysiology is not yet quite clear. Recent studies show a reduction in glutamate level of cerebrospinal fluid in chronic migraineurs, specially,in those with headache resulted from drug overdose. Memantine is an effective drug on the glutamate N-methyl-D-aspartate (NMDA) system that works as a receptor antagonist.In the current study, migraineurs according to IHS diagnostic criteria(18-65 year-old males and females) who had experienced migraine attacks over 2 times a month and had never used prophylactic medications were included. All possible side-effects of the drug were explained to the patients and their consent was obtained. Afterwards, they received10mg/d Memantine or placebo in two randomized groups, and were followed up for 3 months. The primary result was change from baseline at three months in monthly attack frequency. The secondary results indicate the average number of the days with migraine headaches in a month, the average pain severity from 0 to 3 before using painkillers, the kind and dose of the drugs used in each attack, the number of respondents (50% or more reduction in attacks frequency, 50% or more reduction in the number of days experiencing migraine), side-effects (onset, end), severity(mild, average, severe), and risk.MIDAS, SF-12, and HADS will be filled to investigate patients' progress both in the beginning and at the end of the study. If the headache is not treated or is worsening, the patient will be treated by the standard migraine prophylactic medications, and eventually the problem will be detected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120115616N1**
Registration date: **2014-02-11, 1392/11/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-02-11, 1392/11/22

Registrant information

Name

Leila Farsi

Name of organization / entity

Tehran university of medical sciences- Brain and spinal cord injury research center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
pelacebo controlled trial to double blind randomised evaluate memantine efficacy in Migraine without aura patients referred to Imam Khomeini hospital

Public title
Effect of memantine on migraine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients suffering from migrane, according to the diagnostic criteria IHS1, with 2 attacks or more per month, that between their attacks experienced at least 48 hours without headache time, and had never received the drug for migraine prophylaxis for the past 3 months. Exclusion criteria: renal dysfunction; medication overuse headaches according to ICHD-II criteria; use of antipsychotics or antidepressants during the last 3 months; alcohol or drug abuse; allergy to Memantine and its compounds; treatment-resistant acute migraine; pain disorder; severe psychiatric illness; severe infection; malignancy; low survival chance; severe cardiovascular disease; neurodegenerative disorders; pregnancy and lactation; sexually active women of childbearing age that do not use any method of contraception

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

Gender
Both

Phase
3

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
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
Qods Avenu, Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2013-09-22, 1392/06/31

Ethics committee reference number
1300/130/92/د

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 mean number of migraine attacks per month (there must be at least a 48-hour interval between two attacks). Attacks occurred after waking up, or returned in 48 h after anti-migraine drug usage will not be considered separately

Timepoint
Change from baseline at three months in monthly attack frequency

Method of measurement
Use of migraine diary

Secondary outcomes

1

Description
The average number of the days with migraine per month

Timepoint
At the beginning and the end of study

Method of measurement
The average number of the days with migraine per month

2

Description
Number of responders

Timepoint
Months 0,3

Method of measurement
50% or greater reduction in frequency of attacks, 50% or greater reduction in the number of days with migraine

3

Description
The type and number of medications used per attack
Timepoint
Months 0, 3
Method of measurement
Questionary

4

Description
Depression
Timepoint
Months 0, 3
Method of measurement
Hospital anxiety and depression scale

5

Description
Anxiety
Timepoint
Months 0, 3
Method of measurement
Hospital anxiety and depression scale

6

Description
Sleep quality
Timepoint
Months 0, 3
Method of measurement
Pittsburgh sleep quality index

7

Description
The average of pain score in 0-3 days before taking analgesic
Timepoint
Months 0, 3
Method of measurement
Questionary

8

Description
Side Effects
Timepoint
Months 1, 2 and 3
Method of measurement
Severity (mild, moderate, severe) or being dangerous or non-dangerous

9

Description
Functional disability
Timepoint
Months 0, 3
Method of measurement
Migraine Disability Assessment (MIDAS)

10

Description
Quality of life
Timepoint
Months 0, 3
Method of measurement
SF-12

Intervention groups

1

Description
After obtaining informed consent and explaining the possible side effects of medication, patients who have inclusion criteria will be randomized using Randomized Permuted Block and will be divided in two groups. the first group will be treated with Memantine (10 mg daily). Three month after the treatment, patients will be followed up. All patients will receive acute pain treatment.
Category
Treatment - Drugs

2

Description
In the second group, paitients who have inclusion criteria will be treated with placebo at a daily manner. Three month after the treatment, patients will be followed up. All patients will receive acute pain treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Rezvan Norouzzadeh
Street address
Tehran- Keshavarz boulevard- Imam khomeini hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masood Yunesian
Street address
Tehran University of Medical Sciences, Qods street, Keshavarz blv.

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Brain and Spinal Cord Injury Rresearch Center-Tehran University of Medical Sciences
Full name of responsible person
Leila Farsi
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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