Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficacy of low dose topiramate and sodium valporate in migraine prophylaxis

Protocol summary

Summary

Migraine is one of the most common paroxysmal disorders which can disable patients. In this study we are going to compare the efficacy of low dose Topiramate (25 mg twice a day) versus sodium Valporate (200 mg twice a day) in migraine prophylaxis. Patients will be randomly selected in neurology clinic of golestan hospital AHVAZ. A group of 80migrainours who fulfill International Headache Criteria will be enrolled. The patients will be randomly allocated into one of two groups. We will visit them every 4 weeks up to 12 weeks. For evaluation of side effects, we will test CBC, diff, AST, ALT from all patients before and at the end of the treatment course. Severity, duration and frequency of headache, amount of analgesic use and side effects of the drugs in each group will be compared

General information

Acronym

Migraine

IRCT registration information

IRCT registration number: **IRCT201011025076N1**
Registration date: **2011-03-01, 1389/12/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-01, 1389/12/10

Registrant information

Name

Alireza Yarahmadi

Name of organization / entity

Golestan Hospital-Jondi ShapourUniversity of Medical Science and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Ahvaz University of Medical Sciences and Health Services

Expected recruitment start date

2009-05-22, 1388/03/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of low dose topiramate and sodium valporate in migraine prophylaxis

Public title

Comparison of the efficacy of topiramate and sodium valporate in migraine headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Patient’s age between 20 and 45 years, discontinuation of other prophylactic drugs one month prior to study, interval between attacks more than 48 hours Exclusion criteria: pregnancy and breast feeding, non-migraine headaches, overuse of medications in migraine attacks (consumption of NSAID, Ergots & Triptans more than 8 days a month), substance and alcohol abuse, illiteracy of patients and their family (unable to fill diaries) minimal age:20 maximal age:45 sex:female

Age
From **20 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Joundi Shapour University of Medical Science Ahvaz
Street address
Ahvaz, Golestan, Joundi Shapour University of Medical Science and Medical Services
City
Ahvaz
Postal code
45-61355
Approval date
2010-03-08, 1388/12/17
Ethics committee reference number
4993//20/8/p

Health conditions studied

1

Description of health condition studied
Classic migraine
ICD-10 code
G43.1
ICD-10 code description
Classic(with aura)migraine

Primary outcomes

1

Description
Headache severity
Timepoint
On each episode of headache
Method of measurement
The patient registers the severity of her headaches in daily notes according to VAS(FROM 1 TO 10)and these notes are registered by physician monthly

2

Description
headache duration
Timepoint
On each headache episode
Method of measurement
The patient registers the duration of each headache episode and these data are registered by the physician monthly

3

Description
Headaches frequencies
Timepoint
Monthly
Method of measurement
According to patient's notes

4

Description
Analgesic consumption rate
Timepoint
Monthly
Method of measurement
According to patient's notes

Secondary outcomes

1

Description
Clinical side effects
Timepoint
Every 4 weeks
Method of measurement
According to patients daily notes

2

Description
Blood cell count & liver function test changes
Timepoint
Before and at the end of treatment course
Method of measurement
Lab tests

Intervention groups

1

Description
Topiramate tablet(25 mg)twice a day orally for 12 weeks
Category
Treatment - Drugs

2

Description
Sodium valproate tablet(200 mg)twice a day orally for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital, Ahvaz
Full name of responsible person
Alireza Yarahmadi
Street address
Ahvaz, Golestan,Golestan Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Ahvaz Jondishapour University of Medical Sciences and Health Services
Full name of responsible person
Dr. Mostafa Feghhi
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Ahvaz, Golestan,Jondi Shapour University of Medical Science and Health Services
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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, Ahvaz Jondishapour University of Medical Sciences and Health Services
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
Ahvaz Golestan Hospital
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Person responsible for updating data

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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