Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study of the effects of low dose topiramate versus 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 Farabi & Emam Reza hospital of Kermanshah. A group of 56 migrainours 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

IRCT registration information

IRCT registration number: **IRCT138802171856N1**
Registration date: **2009-06-06, 1388/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-06-06, 1388/03/16

Registrant information

Name

Dariush Afshari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

pro_vice_ chancellor for research of Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2009-05-31, 1388/03/10

Expected recruitment end date

2010-09-25, 1389/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of low dose topiramate versus sodium valporate in migraine prophylaxis

Public title

comparison of topiramate and sodium valporate in migraine prophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: more than 4 and less than 10 attacks monthly, patient age at onset of headache less than 50 years, patient’s age between 18-65 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)

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **56**

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
Kermanshah University of Medical Sciences and Health Servises Ethical Comitte

Street address
Shahid Beheshti boulevard, Kermanshah

City
Kermanshah

Postal code

Approval date
2009-04-22, 1388/02/02

Ethics committee reference number
7/420/387

Health conditions studied

1

Description of health condition studied
Common migraine

ICD-10 code
G43.O

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

2

Description of health condition studied
Classical migraine

ICD-10 code
G43.1

ICD-10 code description
Migraine with aura [classical migraine]

Primary outcomes

1

Description
Severity of headache

Timepoint
in each migraine attack

Method of measurement
patient will record the headache severity in daily notes as VAS (from 1 to 10) & physician registers them every 4 weeks

2

Description
Duration of migraine attack

Timepoint
in each migraine attack

Method of measurement
patient records the hours of headache in each attack , physician register them every 4 weeks

3

Description
Headache frequency

Timepoint
every 4 week

Method of measurement
According to patients daily notes

4

Description
Analgesic use

Timepoint
every 4 week

Method of measurement
According to patients daily 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 months
Category
Treatment - Drugs

2

Description
Sodium valporate tablets 200mg twice a day orally, for 12 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital of Kermanshah
Full name of responsible person
Dr Dariush Afshari
Street address
Ashayer boulevard, Dolat Abad, Kermanshah
City
Kermanshah

2

Recruitment center
Name of recruitment center
Emam Reza Hospitl of Kermanshah
Full name of responsible person
Dr Shabnam Rafizadeh
Street address
Sorkhelijeh, Kermanshah
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services
Full name of responsible person
Dr Farid Najafi
Street address
Shahid Beheshti boulevard, Kermanshah
City
Kermanshah
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, Kermanshah 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
Farabi hospital
Full name of responsible person
Dr Dariush Afshari
Position
Neurologist/assistant professor/chairman
Other areas of specialty/work
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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