

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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

Iran (Islamic Republic of)

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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 Services 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

G43.0

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

Kermanshah

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**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Farabi hospital

Full name of responsible person

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Emam Reza hospital

Full name of responsible person

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Position

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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