Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of cinnarizine and topiramate in migraine prophylaxis

Protocol summary

Summary

Migraine is one of the most common paroxysmal headaches which can disable patients. In this study, we are going to compare the efficacy of cinnarizne (25 mg twice a day) versus topiramate (25 mg twice a day) in migraine prophylaxis. In this clinical trial 126 migrainours (according to the International Headache Criteria) who referred to neurology clinic of Emam Reza hospital of Kermanshah, will be randomly allocated into one of the two above mentioned groups. We will visit the patients every 4 weeks up to 12 weeks. Severity, duration and frequency of headache, amount of analgesic use and side effects of the drugs will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201028323N5**
Registration date: **2012-01-10, 1390/10/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-10, 1390/10/20

Registrant information

Name
Nazanin Razazian
Name of organization / entity
Neurology Department of Kermanshah Faculty of Medicine
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cinnarizine and topiramate in migraine prophylaxis

Public title

Comparison of cinnarizine and topiramate in migraine prophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: more than 4 and less than 10 attacks monthly ; interval between attacks more than 48 hours ; age at the onset of headache less than 50 years ; age 18-65 years ; not being pregnant or breast feeding ; discontinuation of other prophylactic drugs one month prior to the study Exclusion criteria: non-migraine headaches ; overuse of medications in migraine attacks (consumption of NSAID, Ergots or 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

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

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, Ethics Committee

Street address

Shahid Beheshti Boulevard, Kermanshah

City

Kermanshah

Postal code

Approval date

2011-10-26, 1390/08/04

Ethics committee reference number

7/420/30525/پ

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

Intervention groups

1

Description

Cinnarizne tablet 25 mg twice a day orally, for 12 weeks

Category

Treatment - Drugs

2

Description

Topiramate tablets 25 mg twice a day orally, for 12

weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospitl of Kermanshah

Full name of responsible person

Dr. Nazanin Razazian

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

Full name of responsible person

Dr. Nazanin Razazian

Position

Assistant Professor, Department of Neurology

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

Full name of responsible person

Dr. Massoud Hamedani

Position

Neurology resident

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