Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of cinnarizine 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 cinnarizne (25 mg twice a day) versus sodium Valporate (200 mg twice a day) in migraine prophylaxis. A total of 98 migrainours who fulfill International Headache Criteria referred to neurology clinic of Emam Reza hospital of Kermanshah, will be randomly allocated into one of the two abovementioned 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: **IRCT201102055729N2**
Registration date: **2011-03-04, 1389/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-04, 1389/12/13

Registrant information

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Arash Bostani
Name of organization / entity
Kermanshah University of Medical Sciences and Health Services
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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2010-10-03, 1389/07/11

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cinnarizine and sodium valporate in migraine prophylaxis

Public title

Comparison of cinnarizine and sodium valporate in migraine prophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: more than 4 and less than 10 attacks monthly, age at the onset of headache less than 50 years, age 18-65 years, discontinuation of other prophylactic drugs one month prior to the 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

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

2010-09-22, 1389/06/31

Ethics committee reference number

7/420/1900203/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

Sodium valporate tablets 200mg 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 Arash Bostani

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

Emam Reza Hospitl of Kermanshah

Full name of responsible person

Dr Arash Bostani

Position

Neurologist/Assistant Professor

Other areas of specialty/work

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Name of organization / entity

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Dr Aref Rajabi

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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