

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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)

Phone

+98 61 1374 3012

Email address

yarahmadi_md@ajums.ac.ir

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 committee 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

City

Ahvaz

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 Fegghi

Street address

Ahvaz, Golestan,Jondi Shapour University of Medical Science and Health Services

City

Ahvaz

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

Full name of responsible person

Dr.Alireza Yarahmadi

Position

Resident of Neurology

Other areas of specialty/work

Street address

No.3, Esfand st, Golestan, Ahvaz

City

Ahvaz

Postal code

61244-65

Phone

+98 61 1320 9024

Fax

+98 61 1374 3012

Email

Yarahmadi_md@yahoo.com;

Yarahmadi_md@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Golestan hospital, Jondi Shapour University of Medical Science and Health Services

Full name of responsible person

Dr.Seyed Ehsan Mohammadiani Nejad

Position

Neurologist/Assistant Professor/chairman

Other areas of specialty/work

Street address

No. 118, Kianpars st., Ahvaz

City

Ahvaz

Postal code

61324-67

Phone

+98 61 1374 3001

Fax

+98 61 1374 3012

Email

Mohammadiani_neuro@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Golestan Hospital

Full name of responsible person

Dr. Vahid Abbasi

Position

Resident of Neurology

Other areas of specialty/work**Street address**

No.6, Day street, Ahvaz

City

Ahvaz

Postal code

61322-12

Phone

+98 61 1374 3008

Fax

+98 61 1374 3013

Email

Abbasi_n@yahoo.com

Web page address**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