

# 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

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## 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

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## 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**

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**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*