

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache in patients referred to Ahvaz Golestan Hospital

#### Protocol summary

##### Summary

In this study efficacy of Levetiracetam comparison with Sodium Valproate in the treatment of Chronic Migraine Headache and if Levetiracetam had an equivalent or better effect (statistically significant) than sodium valproate in reduction of headache severity, frequency and Midas score or fewer complications, Sodium Valproate can be replaced Levetiracetam. Patients 15 to 50 years old referred to Ahvaz Golestan Hospital Neurologic Clinic that according to the criteria of the International Headache Society (IHS) have chronic migraine headache to be put under study, if not pregnancy and history of liver or kidney disease. Initially, 10 patients were divided into two groups according to the results of the pilot study examined and the final sample size is calculated. The patients were randomized block into 2 groups. One group are given Sodium Valproate of Sanofi company whit Depakine comercial name and the other group are given Levetiracetam of Cobel company with Levebel comercial name for 3 months. At the end of the first and third month after the first dose, patients are seen and the efficacy of treatment based on the headache in frequency, intensity and changes in MIDAS scores by their patients with headache severity grading scale from 0 to 10 is recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015022812781N2**

Registration date: **2015-03-12, 1393/12/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-12, 1393/12/21

##### Registrant information

###### Name

Davood Kashipazha

###### Name of organization / entity

Ahvaz JodndiShapour University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1374 3012

###### Email address

kashi-d@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz University Of Medical Sciences

##### Expected recruitment start date

2014-08-23, 1393/06/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache in patients referred to Ahvaz Golestan Hospital

##### Public title

Comparison of efficacy of Levetiracetam with Sodium Valproate in the treatment of Chronic Migraine Headache

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients with chronic migraine headache according to the International Headache Society criteria , (having headache 15 or more days per month with at least 8 days per month fulfilling International Headache Society criteria for migraine for at least 3 months) in the absence of ongoing medication overuse; Women have a negative pregnancy test and have appropriate contraception during the study period; No history of liver disease and kidney; No headaches other than migraine-like headaches included tension headache, sinus headache disorder, structural or post traumatic headache and Exclusion criteria: The incidence of side effects such as gastrointestinal or any other unwanted side effects caused by drug; Do not use the medication in groups for three consecutive days or a week of intermittent.

### **Age**

From **15 years** old to **50 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **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**

Ahvaz University of Medical Sciences

##### **Street address**

Department of Development Studies, Ahvaz  
University of Medical Sciences, Golestan Blvd.

##### **City**

Ahvaz

##### **Postal code**

##### **Approval date**

2014-06-16, 1393/03/26

##### **Ethics committee reference number**

ajums.rec.1393.122

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Migraine

#### **ICD-10 code**

G43.0

#### **ICD-10 code description**

Migraine without aura [common migraine]

### **2**

#### **Description of health condition studied**

Migraine

#### **ICD-10 code**

G43.1

#### **ICD-10 code description**

Migraine with aura [classical migraine]

## **Primary outcomes**

### **1**

#### **Description**

MIDAS Score

#### **Timepoint**

1 and 3 months after starting treatment

#### **Method of measurement**

Based on a standard questionnaire MIDAS

### **2**

#### **Description**

Intensity of headache

#### **Timepoint**

1 and 3 months after starting treatment

#### **Method of measurement**

Pain severity grading scale by the patient with headache severity from grade 0 to 10

### **3**

#### **Description**

Frequency of headache

#### **Timepoint**

1 and 3 months after starting treatment

#### **Method of measurement**

Headache days per month

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention: Levebel 500-1000 mg Oral Twice daily for 3 months

#### **Category**

Treatment - Drugs

**2**

**Description**

Control: Depakine 500-1000 mg Oral Twice daily for 3 months

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz Golestan Hospital Neurologic Clinic

**Full name of responsible person**

Mehrnoush Siavashi

**Street address**

Golestan hospital, Farvardin Avenue, Golestan Street

**City**

Ahvaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Seyed Ahmad Hoseiny

**Street address**

Department of Technology and Research Development, Ahvaz University of Medical Sciences, Golestan Blvd.

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**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**

Mehrnoush Siavashi

**Position**

Resident of Neurology

**Other areas of specialty/work**

**Street address**

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**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Davood Kashipazha/Mehrnoush Siavashi

**Position**

Neurologist/Resident of Neurology

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**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*