

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of the levetiracetam, sodium valproate and propranolol effect in preventing migraine headaches in children with migraine

#### Protocol summary

##### Study aim

Determining of levetiracetam Effect in the prevention of migraine headache in childrens With Migraine

##### Design

This study will be performed on 39 children with migraine headache referred to the pediatric department of Besat hospital and Imam Khomeini clinic of Hamadan, who need to preventive therapy. Patients are assigned to three groups randomly(using the random numbers table).

##### Settings and conduct

This study will be performed on children with migraine headache in Hamadan. Patients will be divided randomly into 3 groups. Each groups will received one preventive therapy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Migraine headache according to ICHD-3 criteria 2-The patients age of 5-15 years 3-The written consent of the patient or his/her parents 4- Patients with normal radiological and neurological findings Exclusion criteria: 1-Recent history of trauma to the head 3-Drug abuse 3-Having a secondary headache due to infection(otitis media, sinusitis,...)

##### Intervention groups

Group 1 (Intervention): Will be treated with oral Levetiracetam tablet, the product of Cobel Darou co, at a dose of 20 mg per kg of body weight, once a day for one month. Group 2 (Control 1): Will be treated with oral Sodium Valproate tablet, the product of Cobel Darou co, at a dose of 10 mg per kg of body weight, once a day for one month. Group 3 (Control 2): Will be treated with oral Propranolol tablet, the product of Cobel Darou co, at a dose of 1 mg per kg of body weight, once a day for one month.

##### Main outcome variables

Headache severity; headache frequency; headache related disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160802029171N3**

Registration date: **2018-02-18, 1396/11/29**

Registration timing: **prospective**

Last update: **2018-02-18, 1396/11/29**

Update count: **0**

##### Registration date

2018-02-18, 1396/11/29

##### Registrant information

##### Name

Afshin Fayazi

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1446 3975

##### Email address

a.fayazi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-05-20, 1397/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the levetiracetam, sodium valproate and propranolol effect in preventing migraine headaches in children with migraine

## Public title

Efficacy of Levetiracetam In pediatrics migrain headache

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Migraine headache according to ICHD-3 criteria The patient's age of 5-15 years Written consent from the patient or his parents/guardians Normal radiological and neurological findings

### Exclusion criteria:

Recent history of head trauma Drug abuse Having a secondary headache due to infection(Otitis media or sinusitis,..)

## Age

From **5 years** old to **15 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **39**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Using of random numbers table

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Reasearch Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Ethics in Research Committee of Hamadan University of Medical Sciences, Hamadan University of Medical Sciences, in front of Mardom park, park intersection

##### City

Hamadan

##### Province

Hamadan

## Postal code

6517838736

## Approval date

2017-11-04, 1396/08/13

## Ethics committee reference number

R.UMSH.REC.1396.532

## Health conditions studied

### 1

#### Description of health condition studied

Migraine

#### ICD-10 code

Migraine

#### ICD-10 code description

G43

## Primary outcomes

### 1

#### Description

Headache Severity: indicates the pain caused by the headache. Grade 0 means no pain, Grade 1 means mild pain, Grade 2 means moderate pain and Grade 3 means severe pain.

#### Timepoint

1 month

#### Method of measurement

Headache severity is measured based on headache score.

### 2

#### Description

Headache frequency: indicates repetition of headache attacks per 24 hours, week or month.

#### Timepoint

1 month

#### Method of measurement

headache frequency will be measured with asking question from patient and his parents.

### 3

#### Description

Headache disability: indicates the number of days that a person can not perform his or her daily tasks due to a headache.

#### Timepoint

1 month

#### Method of measurement

Headache disability will be measured with based on pediatric migraine disability assessment

## Secondary outcomes

### 1

#### Description

Sleepiness: a feeling of being sleepy and lethargic.

**Timepoint**

1 month

**Method of measurement**

Sleepiness will be measured by asking question from childs and/or their parents.

**2****Description**

Agitation: a state of anxiety or nervous excitement

**Timepoint**

1 month

**Method of measurement**

Agitation will be measured by asking question from childs and/or their parents and clinical experiments

**Intervention groups****1****Description**

Intervention group: Will be treated with oral levetiracetam tablet ((S)-2-(2-Oxopyrrolidin-1-yl)butanamide), the product of Cobel Darou company, at a dose of 20 mg/kg of body weight once a day for one month.

**Category**

Prevention

**2****Description**

Control group 1: Will be treated with oral sodium valproate tablet (2-propylpentanoic acid), the product of Cobel Darou Company, at a dose of 10 mg/kg of body weight once a day for one month.

**Category**

Prevention

**3****Description**

Control group 2: Will be treated with oral propranolol tablet (S-1-(isopropylamino)-3-(naphthyloxy)propan-2-ol), the product of Cobel Darou company, at a dose of 1 mg/kg of body weight once a day for one month.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Pediatrics part of Hamadan Besat Hospital

**Full name of responsible person**

Dr. Afshin Fayazi

**Street address**

Department of pediatrics, Besat hospital, Mazdaghineh road, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516735535

**Phone**

+98 81 3838 1491

**Email**

Afshin\_fay@yahoo.com

**2****Recruitment center****Name of recruitment center**

Imam Khomeini clinic of Hamadan

**Full name of responsible person**

Dr. Afshin Fayazi

**Street address**

Imam Khomeini clinic of Hamadan, Mirzadeh Eshghi Street, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516735535

**Phone**

+98 81 3838 1491

**Email**

Afshin\_fay@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Bashirian

**Street address**

Vice-chancellor of research and technology, Hamadan University of Medical Sciences, in front of Mardom park, Park intersection, Hamadan

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516735537

**Phone**

+98 81 3838 1249

**Email**

s-bashirian@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Afshin Fayyazi  
**Position**  
Assistant Professor / Professor of Pediatric Neurology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Pediatrics educational group, School of medicine,  
Hamadan University of Medical Sciences, in front of  
People Park, Park intersection, Hamadan  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6516735537  
**Phone**  
+81 38381491  
**Email**  
Afshin\_fay@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Afshin Fayyazi  
**Position**  
Assistant Professor - Professor of Pediatric Neurology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Pediatrics educational group, School of medicine,  
Hamadan University of Medical Sciences, in front of  
People Park, Park intersection, Hamadan  
**City**  
Hamadan  
**Province**

Hamadan  
**Postal code**  
6516735537  
**Phone**  
+98 38381491  
**Email**  
Afshin\_fay@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Hossein Mansoori  
**Position**  
Assistant of Pediatrics  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Pediatrics educational group, School of medicine,  
Hamadan University of Medical Sciences, in front of  
People Park, Park intersection, Hamadan  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6516735537  
**Phone**  
+98 81 3838 1249  
**Email**  
dr.hosseinmansoori@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Study results will be published for all patients

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available