

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

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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

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

Imam Khomeini clinic of Hamadan

Full name of responsible person

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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

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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
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Assistant Professor / Professor of Pediatric Neurology
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Person responsible for updating data

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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