Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Properanolol 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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+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 pedatrics 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 properanolol 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
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6516735535
Phone
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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
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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
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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

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr. Hossein Mansoori

Position
Assistant of Pediatrics

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Email
dr.hosseinmansoory@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