Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness and ineffectiveness of Prophylactic of Levetiracetam on migraine in 4-14 Years Old Children

Protocol summary

Summary

This study will be done with aim to investigate the prophylactic effects of Levetiracetam on migraine in 4-14 years old children. This study is a single blind clinical trial. The study population will be included all patients with complaints of headache that admitted to Mohammad Kermanshahi hospital of Kermanshah city, the 30 eligible patients by available sampling method is selected and randomly will assigned to an experimental group. In the experimental group, before starting the study the questionnaire of determination of disability due to headache (PedMIDAS) will be provided, then levetiracetam tablets 20 mg per kg body weight), is prescribed and patients with a phone call and if its necessary by referring, every month follow up for at least 6 months and the questionnaire of determination of disability due to headache (PedMIDAS) every 3 months untill 6 months, will be checked. And the frequency and severity of headaches will be checked in compare with before start of treatment. Inclusion criteria: diagnosis of migraine according to ICHD III; written and informed consent of the patient or his guardian. Exclusion criteria: patients with abnormal imaging studies or EEG; a history of recent head trauma or drug abuse; having a secondary headache to infection (sinusitis, of otitis media, ...); and patients who coincident suffered from seizures and mood disorders ; being abnormal neurological examination

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101714333N44**
Registration date: **2015-11-03, 1394/08/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-03, 1394/08/12

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

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

Effectiveness and ineffectiveness of Prophylactic of Levetiracetam on migraine in 4-14 Years Old Children

Public title

Prophylactic Effects of Levetiracetam on Migraine in 4-14 Years Old Children

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of migraine according to ICHD III; written and informed consent of the patient or his guardian. Exclusion criteria: patients with abnormal imaging studies or EEG; a history of recent head trauma or drug abuse; having a secondary headache to infection (sinusitis, of otitis media, ...); and patients who coincident suffered from seizures and mood disorders ; being abnormal neurological examination

Age
From **4 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

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 Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2014-07-01, 1393/04/10

Ethics committee reference number
13871/7/420/پ

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache frequency

Timepoint
Beginning of the study, 1 ,3 and 6 months after study

Method of measurement
With the question of patient

2

Description
The severity of migraine headaches

Timepoint
Beginning of the study, 1 ,3 and 6 months after study

Method of measurement
Based on questionnaire of determination of disability due to headache (PedMIDAS)

3

Description
Duration of headaches

Timepoint
Beginning of the study, 1 ,3 and 6 months after study

Method of measurement
With the question of patient

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group, before starting the study the questionnaire of disability due to headache (PedMIDAS) will be provided, then levetiracetam tablets 20 mg per kg body weight), is prescribed and patients with a phone call and if its necessary by referring, every month follow up for at least 6 months and the questionnaire of disability due to headache (PedMIDAS) every 3 months untill 6 months, will be checked. And the frequency and severity of headaches will be checked in compare with before start of treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Mohammad Kermanshah
Full name of responsible person
Bahare Yavari
Street address
Mohammad Kermanshahi Hospital, Crossroads of Shirkhorshid
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
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, Kermanshah 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Sedighi Mostafa
Position
Child Neurologist
Other areas of specialty/work
Street address
Mohammad Kermanshahi Hospital, Crossroads of Shirkhorshid
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Fax
Email
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Web page address

Person responsible for updating data

Contact

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