

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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

City

kermanshah

Postal code

6715847134

Phone

+98 83 3721 8204

Fax**Email**

sedighi_mostafa@yahoo.com

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