

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effectiveness of levetiracetam and placebo in improving migraine frequency and duration in children aged 4-17 years old.

Protocol summary

Study aim

Determination of efficacy and side effects of levetiracetam versus placebo in prevention of migraine headache in 4-17 years old children

Design

Randomized double-blind placebo-controlled trial

Settings and conduct

It conducted in Children's Medical Center, Tehran University of Medical Sciences, Tehran, Iran. Levetiracetam and placebo were administered to patients in random. Investigators, patients and their parents were blinded during the study

Participants/Inclusion and exclusion criteria

Children between 4 to 17 years old. Inclusion criteria: Diagnosis of migraine with or without aura according to international headache society criterion: severe educational or daily dysfunction with one or more migraine headaches in a week or frequency of attacks more than 4 times in a month. Exclusion criteria: Chronic headache or complicated migraine; presence of other neural or systemic disorders; previous known allergy to levetiracetam; contraindication of drug due to occurrence of it's side effects;

Intervention groups

Levetiracetam and placebo used in patients suffered from migraine

Main outcome variables

Headache frequency and headache intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021632603N1**

Registration date: **2017-07-17, 1396/04/26**

Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **1**

Registration date

2017-07-17, 1396/04/26

Registrant information

Name

Hadi Montazer Lotf Elahi

Name of organization / entity

Tehran University Of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, tehran university of medical science

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-07-11, 1396/04/20

Actual recruitment start date

2017-07-20, 1396/04/29

Actual recruitment end date

2018-04-09, 1397/01/20

Trial completion date

2018-08-16, 1397/05/25

Scientific title

Comparison of the effectiveness of levetiracetam and placebo in improving migraine frequency and duration in children aged 4-17 years old.

Public title

Levetiracetam for the prophylactic treatment of pediatric migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 4-17 years met the diagnostic criteria for pediatric migraine (with or without aura) as defined by the International Headache Society having at least 4 migraineous episodes per month or have severe disabling or intolerable headache

Exclusion criteria:

History of cluster headache, hemiplegic migraine, or chronic daily headaches Headaches related to structural brain lesions Presence of focal neurologic deficit No therapeutic response with at least 3 adequate trials of medication for headache prophylaxis History of levetiracetam sensitivity Pregnancy Other neurological conditions (e.g. epilepsy)

Age

From **4 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **68**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants were randomly assigned to receive either levetiracetam or placebo in a 1:1 ratio by permuted block randomization (block sizes of four) via an interactive web response system.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study medications were coded and administered by a nurse who was not informed about the clinical characteristics of cases. Investigators, participants, and their parents were blinded during the course of the study until the code was broken at the end of the trial.

Packaging, size, shape, and placebo color were all similar to levetiracetam

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical science

Street address

Beside Ghods street, keshavarz avenue, Tehran

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Tehran

Postal code

1417653761

Approval date

2016-10-23, 1395/08/02

Ethics committee reference number

IR.TUMS.VCR.REC.1395-818

Health conditions studied

1

Description of health condition studied

migraine headache

ICD-10 code

G43.0

ICD-10 code description

migraine without aura or classic migraine

Primary outcomes

1

Description

Migraine frequency

Timepoint

before initiation of trial and then per 4 weeks

Method of measurement

Headache frequency was defined as the number of attacks that fulfilled the International Headache Society criteria. In each arm, we obtained the mean number of these episodes every 4 weeks after initiation of treatment.

2

Description

migraine intensity

Timepoint

before initiation of trial and then per 4 weeks

Method of measurement

visual analogue scale (VAS)

Secondary outcomes

1

Description

Efficacy (More than 50% responder rate)

Timepoint

Baseline and the last 4 weeks of double-blind phase

Method of measurement

For this purpose we used headache diary so the migraine frequency of baseline phase and the last 4 weeks of double-blind phase were achieved. >50% responder rate shows the efficacy of levetiracetam and placebo in the prevention of migraine. In fact, The drug was effective if it could decrease the migraine frequency by more than 50% in double-blind phase compared with the baseline frequency. "

2

Description

side effects

Timepoint

monthly visits and immediately after occurrence of alarms

Method of measurement

Taking history

Intervention groups

1

Description

A- Intervention group: 34 patients that they have essential criteria will arrive at this investigation randomly after code reception and getting subscription from them. patients don't know that they are in intervention or control group and interviewer is not aware that patient get drug or placebo and data collection will achieve with patient coding before starting of intervention. patients information (signs, symptoms, frequency and severity of headaches, duration of disease, duration of attacks and response to acute treatment) is registered in questionnaire. In this group Levetiracetam that exist in 250 and 500 mg tablets is administered at 20 mg/kg/day and is increased to 40 mg/kg/day in next visit if needed according to sign and symptoms. (routinely half or one tablet twice a day according to child's weight). treatment's duration is 3 months. patients are visited monthly and progressed note is complete for them and we exit them from study if complications happen or they dispense. Acute headache attacks is control with acetaminophen. Levetiracetam is the S- enantiomer of etiracetam with this chemical name: " S-alpha-ethyl-2-oxo-1-pyrrolidin ". It's bioavailability is 100%; it's biological half life is 6-8 hrs and it has urinary excretion; it's formula is C₈H₁₄N₂O₂ and it's molar mass is 170.209 g/mol. Levetiracetam is an anti convulsion drug with little side effects and common side effects including: insomnia, somnolence, restlessness, mood or behavioral disorders and skin rash. This drug secrete in milk and it's use in pregnancy should be with caution. Levetiracetam as an anti convulsive drug is start at 20 mg/kg/day divided in 2 doses and is increased up to 60 mg/kg/day; it's use dose not interact with food; it's oral absorption is complete and rapid and arrives to appropriate blood level during 2 days. This drug exist in form of syrup, slow

release tablets also intra venous form. we use in this study 250 and 500 mg tablets that are made in Iran (" Cobel daro company") with " Levebel" name. In pediatric medicine anti convulsive drugs are a group of relatively safe drugs in migraine headache prevention and Levetiracetam is a most safe drugs of them also there is a little investigations by Levetiracetam in migraine headache prevention.

Category

Treatment - Drugs

2

Description

B- control group: 34 patients that they have essential criteria will arrive at this investigation randomly after code reception and getting subscription from them. patients don't know that they are in intervention or control group and interviewer is not aware that patient get drug or placebo and data collection will achieve with patient coding before starting of intervention. patients information (signs, symptoms, frequency and severity of headaches, duration of disease, duration of attacks and response to acute treatment) is registered in questionnaire. In this group Placebo is administered for patients. Placebo is exactly the same of 250 or 500 mg tablets of Levetiracetam (with shape, color, weight and size) and is made in "cobel daroo company". Placebo is administered for patients according to their weight at half or one tablet (small or medium size tablet); twice a day. treatment's duration is 3 months. patients are visited monthly and progressed note is complete for them and we exit them from study if complications happen or they dispense. Acute headache attacks is control with acetaminophen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric medical center

Full name of responsible person

Mrs Frootan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran university of medical science

Full name of responsible person

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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

Vice chancellor for research, Tehran university of medical science

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**

Tehran university of medical science

Full name of responsible person

Montazerlotfelahi-Hadi

Position

Pediatric neurologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected information can be shared

When the data will become available and for how long

After the publication of results

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Our data can be used with our permissions in academic classes

From where data/document is obtainable

Hadi Montazerlotfelahi with E-mail: h-mlotfelahi@razi.tums.ac.ir

What processes are involved for a request to access data/document

After a month we can share the data after complete understanding of aims

Comments