

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

A comparative study on the efficacy of levetiracetam and amitriptyline in childhood migraine; An open-label randomized controlled trial

Protocol summary

Study aim

Determine and compare the efficacy of levetiracetam and amitriptyline in the treatment of migraine headaches in children.

Design

Two arm parallel group open-label randomized controlled trial

Settings and conduct

The patients will be referred to our operator by the pediatric neurologists that are working at university clinics. Then, the patients and their parents will be registered and fill out prepared questionnaires. In the questionnaires; the frequency and severity and period of headaches should be recorded daily by the patients and their parents. These findings will be evaluated along with the quality of life (PedMidas) at the end of the pre-randomized phase, and also at the end of each month of treatment. Compared to the baseline records, if 50 percent or more decrease in symptoms is observed, it will be considered as a positive response to the medical treatment, and so, the treatment process will be continued until the end of the study.

Participants/Inclusion and exclusion criteria

All children with migraines who develop migraine attacks at least four times a month, or interfere with daily activities, are able to enter this study; Cases of epilepsy, the presence of migraine with a complication, hypersensitivity to tricyclic antidepressant drugs, the lack of ability to record data, the use of other prophylaxis other than levetiracetam and amitriptyline, severe psychiatric problems, taking analgesic more than 4 times a week for migraine headache, will not go into the study.

Intervention groups

Children aged 5 to 15 years old who are classified as migraine under the International Classification of Headache Disorders (ICHD) are placed in one of the treatment groups (levetiracetam or amitriptyline) and the response to the treatment will be evaluate.

Main outcome variables

Duration of headache, headache frequency, headache severity, quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171212037850N1**

Registration date: **2018-05-01, 1397/02/11**

Registration timing: **retrospective**

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

Registration date

2018-05-01, 1397/02/11

Registrant information

Name

Gholamreza Jelodar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3445 6272

Email address

jelodar-g@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the efficacy of levetiracetam and amitriptyline in childhood migraine; An open-label randomized controlled trial

Public title

Levetiracetam in migraine headaches of children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All of children with migraine headache with or without aura, at least two attack per week or four attack per month, so that the attacks cause them to consume the analgesics or interfere with everyday activities

Exclusion criteria:

Epilepsy Complicated migraine Not having the ability to record data related to the number, duration, and severity of headaches Use of other prophylactic drugs other than Levetiracetam and Amitriptyline Severe psychiatric problems like depression and ADHD Hypersensitivity to tricyclic anti depressants drugs Taking analgesic more than 4 times a week for migraine headache

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After the patients were selected for inclusion in the study, they would be randomly divided into two groups A and B, in the form of quadruple blocks using the Block Balanced Randomization Method. Neither researchers nor patients will know which patients will belong to which group and when administering the medicine, patients will be assigned to one of the groups A or B (Levetiracetam or Amitriptyline) on the basis of the block list.

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**

Ethics committee of Isfahan University of Medical Sciences

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Imam Hossein Children's Medical Education Center, Imam Khomeini Blvd. Daneshgah Square

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Postal code

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Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.mui.rec.1396.3.781

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Duration of headache

Timepoint

Before, one month later, two months later and three months after treatment began

Method of measurement

Daily Headache Registration Form

2**Description**

Headache severity

Timepoint

Before, one month later, two months later and three months after treatment began

Method of measurement

Wong-Baker FACES Pain Rating Scale

3**Description**

Headache frequency

Timepoint

Before, one month later, two months later and three months after treatment began

Method of measurement

Record daily diary of headache

4

Description

Improving the quality of life

Timepoint

Before, one month later, two months later and three months after treatment began

Method of measurement

PedMIDAS quality of life checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Levetiracetam with a starting dose of 10 mg / kg given at a dose of 20 mg / kg in a week. In children and adults, the maximum dose is 3000 mg per day before bedtime, given for three months.

Category

Treatment - Drugs

2

Description

Control group: Amitriptyline is given at a dose of 5 to 12 mg / day and increases to 0.25 mg / kg / day for 2 weeks to reach the required dose of 1 mg / kg / day. The drug is given as a single dose at night.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

pediatric neurology clinics of Isfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Ghazavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Jelodar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Position

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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

No more information

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Information on the main consequence of sharing is possible.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Researche

From where data/document is obtainable

Gholamreza Jelodar jelodar-g@ajums.ac.ir
00989166133744

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

Sending an email and mentioning the job, job position and purpose of the request

Comments