Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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Iran (Islamic Republic of)
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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

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

City
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Isfehan

Postal code
۸۱۹۵۱۶۳۳۸۱

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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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Gholamreza Jelodar

Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Other areas of specialty/work

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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