Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of comparison of the effects of propranolol and levetiracetam to prevent migraine attacks in 5-15 year-old children

Protocol summary

Study aim
This clinical trial before and after study is carried out with the aim of evaluating the prophylactic effect of Levetiracetam on pediatric migraine and its comparison with propranolol

Design
A clinical trial with control group, with parallel groups, randomized and 30 patients in each group

Settings and conduct
The study will be performed in Neurology clinic of Bouali Hospital of Sari and the patients are non-blinded.

Participants/Inclusion and exclusion criteria
Age 5 to 15 years, migraine attacks more than once a week causing the child's disability (PedMIDAS score > 20) and headache prophylaxis is required in the child

Intervention groups
In the intervention group, the Levetirastam tablet with brand name of Levebel made by Koobl Daroo Co. at a daily dose of 20 mg/kg is prescribed for 3 months and in control group, 0.5-1 mg/kg Propranol tablet made by the same company is prescribed in two divided doses.

Main outcome variables
After 3 months and then 6 months, the severity, duration, number of headache attacks per month, the rate of headache disability and the side effects of medications are evaluated.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090412001808N5**
Registration date: **2018-03-22, 1397/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-22, 1397/01/02**
Update count: **0**

Registration date
2018-03-22, 1397/01/02

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-20, 1396/12/29

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of comparison of the effects of propranolol and levetiracetam to prevent migraine attacks in 5-15 year-old children

Public title
effects of propranolol and levetiracetam to prevent migraine attacks in children 5-15 year-old children

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:

Age 5 to 15 years migraine attacks headache more than once a week Headache causing a child's disability (PedMIDAS score more than 20) Headache prophylaxis is required in the child

Exclusion criteria:

Underlying diseases such as asthma, liver disease, diabetes Secondary headaches or other neurological disorders such as epilepsy receiving medications for migraine over the past two months History of sensitivity to propranolol and levetiracetam history of propranolol and levetiracetam for migraine prophylaxis renal dysfunction

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized method is simple and by using random numbers' table

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 Mazandaran University of Medical Sciences

Street address

Deputy of Science and Technology of Mazandaran University of Medical Sciences, Moallem square, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

48178-44718

Approval date

2017-08-07, 1396/05/16

Ethics committee reference number

IR.MAZUMS.REC.1396.2937

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headache severity

Timepoint

The beginning of the study, the 3rd month and the 6th month

Method of measurement

Visual Analogue Scales (From a score of 1-10 that is scored by the child)

2

Description

Headache duration

Timepoint

The beginning of the study, the 3rd month and the 6th month

Method of measurement

minute

Secondary outcomes

1

Description

Number of migraine attacks per month

Timepoint

The beginning of the study, the 3rd month and the 6th month

Method of measurement

Number in the questionnaire

2

Description

Side effects of medication (Dizziness, drowsiness, weight loss, anorexia, memory impairment, imbalance, skin complications)

Timepoint

The 3rd month and 6th month

Method of measurement

Questionnaire

3

Description

Severity of disability due to headache

Timepoint

The beginning of the study, the 3rd month and the 6th month

Method of measurement

Questionnaire (Grade 1: Score 0-10, Grade 2: Score 11-30, Grade 3: Score 31-50 and Grade 4: Scores above 50)

Intervention groups

1

Description

Intervention group: In the intervention group, the Levetirastam tablet with brand name of Levebel made by Koobl Daroo Co. at a daily dose of 20 mg/kg is prescribed for 3 months.

Category

Prevention

2

Description

Control group: In control group, 0.5-1 mg/kg Propranol tablet made by Koobl Daroo Co. is prescribed in two divided doses for 3 months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Bouali hospital of Sari

Full name of responsible person
Ali Abbaskhanian

Street address
Bouali hospital, Pasdaran blvd., Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Majid Saeidi

Street address
Bouali hospital, Pasdaran Blv, Sari, Iran

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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

Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Shiva Shadani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Position
Associate professor
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Person responsible for updating data

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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
Part of the data is available
When the data will become available and for how long
starting in January 2025
To whom data/document is available
All people
Under which criteria data/document could be used
Nothing
From where data/document is obtainable
Please call Shiva Shadani: +98 912 596 4629
Email:shiva_shadani@yahoo.com
What processes are involved for a request to access data/document
After a call, information is sent within a few days
Comments