

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 Levetiracetam 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 Propranolol 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

###### Name

Ali Abbaskhanian

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1223 3010

###### Email address

aabbaskhanian@mazums.ac.ir

##### 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 Propranolol 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

##### City

Sari

##### Province

Mazandaran

##### Postal code

48158-38477

##### Phone

+98 11 3334 2334

##### Email

aabbaskhanian@mazums.ac.ir

## 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

##### City

Sari

##### Province

Mazandaran

##### Postal code

48178 -44718

##### Phone

+98 11 3334 2334

##### Email

msaeedi@mazums.ac.ir

#### 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

##### Street address

Bouali hospital, Pasdaran blvd., Sari, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

38477-48158

##### Phone

+98 11 3334 2334

##### Email

shiva\_shadani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Ali Abbaskhanian

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

**Street address**

Bouali hospital, Pasdaran blvd., Sari, Iran

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**Email**

shiva\_shadani@yahoo.com

**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****Person responsible for updating data****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

**Street address**

Bouali hospital, Pasdaran blvd., Sari, Iran

**City**

Sari

**Province**

Mazandaran