

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of therapeutic effects and monotherapy with lacosamide versus carbamazepine in children with newly diagnosed epilepsy

Protocol summary

Study aim

Comparison of therapeutic effect and monotherapy with lacosamide against carbamazepine in children with newly diagnosed epilepsy

Design

Clinical trial with 2 parallel groups, open-label, randomized, phase 3 on 100 patients. The random allocate software was used for randomization.

Settings and conduct

Children with newly diagnosed epilepsy who are hospitalized in Bu Ali Sina Hospital will be randomly divided into two groups A and B. Group A will receive lacosamide and group B will receive carbamazepine. Demographic information and clinical conditions of the patients will be recorded before entering the study, and then in the follow-up visits every three months, the two groups will be compared with each other in terms of recovery and complications.

Participants/Inclusion and exclusion criteria

The inclusion criteria of the study are children between the ages of 4 and 16 who have newly been diagnosed with epilepsy. exclusion criteria: 1. History of liver disease or heart disease 2. Receiving anti-seizure medication for more than 48 hours during the last three months 3. Patients with any neurodegenerative or neurometabolic disease 4. history of hypersensitivity reaction 5. Lack of consent of the patient and the patient's guardian 6. Patients with a history of bone marrow suppression

Intervention groups

Group A: Lacosamide Group B: carbamazepine

Main outcome variables

Primary outcome: at least a 6-month seizure-free period. Secondary outcome: drug side effects (aplastic anemia - agranulocytosis - liver dysfunction (increase of AST, ALT above 5 times the normal range) - hyponatremia (Na less than 135).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231123060147N1**

Registration date: **2024-01-12, 1402/10/22**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-12, 1402/10/22**

Update count: **0**

Registration date

2024-01-12, 1402/10/22

Registrant information

Name

Paniz Balmeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 1367

Email address

alipourvavsari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-10, 1402/09/19

Expected recruitment end date

2024-02-08, 1402/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects and monotherapy with lacosamide versus carbamazepine in children with newly diagnosed epilepsy

Public title

Investigation of therapeutic effect and monotherapy with lacosamide compared to carbamazepine in children with epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged between 4 and 16 years with newly diagnosed epilepsy

Exclusion criteria:

History of liver disease and history of heart disease
Receiving antiepileptic medication for more than 48 hours during the last three months
Patients with any neurodegenerative or neurometabolic disease causing an allergic reaction
Dissatisfaction of the patient and the patient's parents
Patients with a history of bone marrow suppression

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyst

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding in this study will be as follows, so that at the beginning of the study, an envelope that has only one code on it is randomly given to them, and the type of treatment group is determined in the envelope, and the envelope is opened by the pharmacy and the drug is already prepared and delivered to the patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Mazandaran University of Medical Sciences

Street address

Sari, Imam Square, Serah Joibar, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

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Approval date

2023-10-24, 1402/08/02

Ethics committee reference number

IR.MAZUMS.REC.1402.466

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

At least a period of 6 months without seizures

Timepoint

For 6 months, the number and type of seizures experienced by the child from the previous visit will be asked

Method of measurement

Observing types of seizures by parents

Secondary outcomes

1

Description

Drug side effects includes (aplastic anemia - agranulocytosis - liver disorder (increased AST, ALT more than 5 times the normal range) - hyponatremia (Na less than 135).

Timepoint

6 months after drug intervention

Method of measurement

Observation of drug complications includes (aplastic anemia - agranulocytosis - liver dysfunction (increase of AST, ALT above 5 times the normal range) - hyponatremia (Na less than 135).

Intervention groups

1

Description

Intervention group: Lacosamide (Unimide brand) was started with a daily dose of 2 mg/kg/day divided into two doses (BD) and continued with an increase of 2 mg/kg/day every week to a maximum dose of 10 mg/kg/day if tolerated.

Category

Treatment - Drugs

2

Description

Intervention group: Carbamazepine (brand name Tegatard) with a dose of 5 mg/kg/day (BD) during the first week and with an increase of 5 mg/kg/day every week to a maximum dose of 20 mg/kg/day if tolerated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Sina Hospital

Full name of responsible person

Kobra Sheidaee

Street address

Mazandaran, Sari, Pasdaran Blvd., Bo Ali Sina Medical Education Center

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4815838477

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user.k.s4834@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

Street address

Mazandaran Province, Sari City, Moalem Square, Research and Technology Deputy Building

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pajhooheshi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Kobra Sheidaee

Position

Assistant Professor of Pediatric Neurology

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

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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

There is no more information There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Kobra Sheidaee

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Neurology

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