Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Lacosamide on EEG Interictal Epileptiform Discharges of Children with Epilepsy.

Protocol summary

Study aim
determining the effect of Lacosamide on reducing interictal epileptiform discharges on children with epilepsy

Design
In all patients participating in the study, Lacosamide will be added to their previous drugs (the EEG before and after taking the drug is compared and we do not have a control group).

Settings and conduct
we add Lacosamide (lacosa) to their previous drugs with an initial dose of 2mg/kg, which is increased to a dose of 8mg/kg within 4 weeks. EEG will be repeated for all children before starting treatment with lacosamide and 1 month after starting treatment. . EEG is taken for 20 minutes and the intensity of epileptic waves including the number of epileptic waves in waves per minute and the duration of epileptic waves will be calculated to the total time of EEG. EEG will be taken and interpreted by an expert and blind. The number of seizure recurrences in a month will be collected in the prepared checklist. Observed complications are recorded. The possible side effects of the drug, which are based on the drug brochure, such as dizziness, tingling in the legs, blurred vision, nausea, vomiting, drowsiness, loss of balance, and memory problems, will be recorded for each participant.

Participants/Inclusion and exclusion criteria
Children with idiopathic or symptomatic epilepsy with an age range of 4 to 15 years The presence of epileptic waves in at least 50% of the initial EEG

Intervention groups
For all eligible patients (4 to 15-year-old children with epilepsy who have epileptic waves in at least 50% of the initial EEG), lacosamide tablets (lacsa) are prescribed in addition to the drugs they were already taking. EEG will be repeated for all children before starting treatment with lacosamide and 1 month after starting treatment.

Main outcome variables
using Lacosamide to decrease interictal epileptiform discharges in children with epilepsy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120821010634N5**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information

Name
Afshin Fayazi

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-04, 1403/08/14

Expected recruitment end date
2025-04-20, 1404/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Lacosamide on EEG Interictal Epileptiform Discharges of Children with Epilepsy.

Public title

The Effect of Lacosamide on EEG Interictal Epileptiform Discharges of Children with Epilepsy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with idiopathic or symptomatic epilepsy with an age range of 4 to 15 years The presence of epileptic waves in at least 50% of the initial EEG

Exclusion criteria:

Children younger than 4 years old or older than 15 years old Children with absence or similar epilepsy in which there are contraindications for taking drugs like lacosamide.

Age

From **4 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Deputy of research, Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

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Province

Hamadan

Postal code

6517838678

Approval date

2024-11-03, 1403/08/13

Ethics committee reference number

IR.UMSHA.REC.1403.551

Health conditions studied

1

Description of health condition studied

Effect of Lacosamide on EEG of Children with Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

number of epileptiform discharges on EEG

Timepoint

before starting the trial and 1 month after that

Method of measurement

Electrophysiological data will be collected by an EEG data recorder (24-channel Ebenevo device).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All people participating in the trial will be given lacosamide drug, and before receiving the drug and one month after that, an EEG will be taken from them, and the number of epileptiform discharges in these two EEGs will be compared.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Fayazi's Pediatric Neurology Office

Full name of responsible person

Afshin Fayazi

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Parvin Etisami 2 Alley, Mirzadeh Eshghi St.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

General information including the age and gender of people in the participating groups and the factors affecting the effectiveness of the drug will be published, and other information will be provided to other researchers at the discretion of the person in charge of the research and after reviewing the requests one by one.

When the data will become available and for how long

It will be possible to access the information from 1403 until two years after the publication of the results

To whom data/document is available

Researchers who want to do additional research in this field.

Under which criteria data/document could be used

The data published in the article will be available to the public at the discretion of the journal. Other information will be available to the researcher at the discretion of the professor in charge of the research and after reviewing the requests one by one.

From where data/document is obtainable

Refer to the professor in charge of the research.

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

An e-mail will be sent to the professor in charge of the research, and the information file will be provided to the researcher if the relevant professor decides.

Comments