

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 (lacosam) 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 (lacosam) 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

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0075

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afshin_fay@yahoo.com

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
Hamadan

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
Street address
Parvin Etisami 2 Alley, Mirzadeh Eshghi St.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Khazayi
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Hamedan University of Medical Science, Shahid
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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
Full name of responsible person
Afshin Fayazi
Position
consultant
Latest degree
Subspecialist

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Person responsible for updating data

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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