

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

##### Email address

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.  
**City**

Hamedan  
**Province**  
Hamadan  
**Postal code**  
6517838736  
**Phone**  
+98 81 3826 5630  
**Email**  
Afshin\_Fay@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Khazayi  
**Street address**  
Hamedan University of Medical Science, Shahid  
Fahmideh.St.  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
6517838736  
**Phone**  
+98 81 3838 2112  
**Email**  
Afshin\_Fay@yahoo.com  
**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

**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Hamedan University of Medical Sciences  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
6517838736  
**Phone**  
+98 81 3838 1796  
**Fax**  
**Email**  
Afshin\_Fay@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Afshin Fayazi  
**Position**  
consultant  
**Latest degree**  
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6517838736  
**Phone**  
+98 81 1264 0075  
**Fax**  
+98 81 1264 0075  
**Email**  
afshin\_fay@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Afshin Fayazi  
**Position**  
consultant  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Hamedan University of Medical Sciences, Shahid  
Fahmideh Blvd., pajoohesh Square  
**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838736

**Phone**

+98 81 3826 5630

**Email**

Afshin\_Fay@yahoo.com

## 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**