

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Efficacy of lacosomide on refractory focal seizures as add on therapy in children aged 6 months to 16 years

#### Protocol summary

##### Study aim

Efficacy of lacosomide on refractory focal seizures as add on therapy in children aged 6 months to 16 years in Imam Hossein Children's Hospital in Isfahan in 2020

##### Design

Clinical trial, single group, non-blind, phase 2 on 44 patients

##### Settings and conduct

The samples include children with focal seizures referred to the neurology clinic of Imam Hossein Specialized Hospital in Isfahan who meet the inclusion criteria. Due to the limited number of patients according to the inclusion and exclusion criteria, sampling by available method and quota in age groups (less than 6 years / 6 to 12 years / more than 12 years) and sex (male / Female) until reaching the sample size of 44 people.

##### Participants/Inclusion and exclusion criteria

All children from 6 months to 16 years of age with focal seizures who have been diagnosed with at least one previous electroencephalogram and do not respond well to routine treatments and despite appropriate treatment with at least two anticonvulsant drugs (as defined by refractory seizures in Nelson's book (2) had at least two relapses in four weeks during the 8 weeks prior to enrollment and no three-week period was in complete control. Do not enter the study with the consent of the legal guardian or sponsor

##### Intervention groups

All children from 6 months to 16 years of age with focal seizures who have been diagnosed with at least one previous electroencephalogram and do not respond well to routine treatments and despite appropriate treatment with at least two anticonvulsant drugs

##### Main outcome variables

At the end of the study, lacosomide is expected to be effective on refractory focal seizures as an add on therapy in children aged 6 months to 16 years in Imam Hossein Children's Hospital in Isfahan.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211104052968N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **retrospective**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

##### Registration date

2021-11-13, 1400/08/22

##### Registrant information

##### Name

Taybeh Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 7467 3461

##### Email address

dr.t.mohammadi2020@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-30, 1399/10/10

##### Expected recruitment end date

2021-07-01, 1400/04/10

##### Actual recruitment start date

2021-02-28, 1399/12/10

##### Actual recruitment end date

2021-09-01, 1400/06/10

##### Trial completion date

2021-09-02, 1400/06/11

##### Scientific title

Efficacy of lacosomide on refractory focal seizures as add on therapy in children aged 6 months to 16 years

**Public title**

Efficacy of lacosomide on refractory focal seizures

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All children from 6 months to 16 years of age with focal seizures who have been diagnosed with at least one previous electroencephalogram and do not respond well to routine treatments despite appropriate treatment with at least two anticonvulsants within 8 weeks of enrollment. They have had at least two relapses in four weeks and have not been in complete control for three weeks, and have not changed their doses of other anticonvulsant drugs in the two weeks prior to enrollment.

**Exclusion criteria:**

Previous administration of lacosamide as an anticonvulsant for at least two months prior to the examination renal disease Inability to tolerate the drug due to side effects Seizures caused by a progressive brain or neurodegenerative disease

**Age**

From **6 months** old to **16 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

Actual sample size reached: **44**

**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 Isfahan University of Medical Sciences

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2021-01-25, 1399/11/06

**Ethics committee reference number**

IR.MUI.MED.REC.1399.1163

**Health conditions studied****1****Description of health condition studied**

seizure

**ICD-10 code**

G40

**ICD-10 code description**

ICD-10-CM

**Primary outcomes****1****Description**

Reducing the severity and severity of seizures in children 6 months to 16 years according to the definition of refractory seizures in Nelson's book

**Timepoint**

Patients' seizures were monitored after the drug reached the therapeutic dose, which is six weeks, and then three months later.

**Method of measurement**

The severity of seizures as a percentage and includes 8 categories 0 - 25, 25-50, 50 to 75 and 75 to 100% in the range of negative to positive 100% based on the initial rate of seizures

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences-Imam Hossein Hospital

**Full name of responsible person**

Jafar Nasiri

**Street address**

Imam Khomeini St. - Before Esteghlal Square - Imam Hossein Children's Educational and Medical Center

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۸۱۹۵۱۶۳۳۸۱

**Phone**

+98 31 3386 6090

**Fax**

+98 31 3386 8286

**Email**

emamhossein\_hospital@mui.ac.ir

**Web page address**<https://ehuch.mui.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghaygh haghjoo javanmard

**Street address**

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**Web page address**<https://research.mui.ac.ir/fa/dr.haghjoo>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Taybeh Mohammadi

**Position**

Subspecialized assistant Pediatric Neurology

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 81 7467 3461

**Fax****Email**

dr.t.mohammadi2020@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Nasiri Jafar

**Position**

Associate Professor of Pediatric Neurology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

Nasiri.jafar@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Taybeh Mohammadi

**Position**

Subspecialized assistant Pediatric Neurology

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 81 7467 3461

**Fax**

**Email**

dr.t.mohammadi2020@gmail.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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

In this study, statistical data (mean, minimum and maximum) of demographic variables of all samples and not individually studied can be published and the results of drug effectiveness after data analysis can be published without mentioning the names and details of individuals.

**When the data will become available and for how long**

Start the access period after publishing the results

**To whom data/document is available**

All scientific and academic researchers with mentioning the name and scientific affiliation

**Under which criteria data/document could be used**

Using the method of studying and analyzing data and results with the permission of the authors or scientific citations in journals, articles and sources is allowed.

**From where data/document is obtainable**

To the corresponding author whose email details were given and also specified in the relevant articles

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

The request will be sent by email. After consulting with the other authors and agreeing to sponsor the project, the information that can be published will be made available to another person or organization.

**Comments**