Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

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

Protocol summary

Study aim
Effcacy 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

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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

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

Public title
Effcacy 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 deaseies 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
Isfehan
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 Hospitall

Full name of responsible person
Jafar Nasiri
Street address
Imam Khomeini St. - Before Esteghlal Square - Imam Hossein Children's Educational and Medical Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghaygh haghjoo javanmard
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Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4
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Web page address
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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
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
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Person responsible for updating data

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Subspecialized assistant Pediatric Neurology

Latest degree

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Other areas of specialty/work

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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