

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Safety and Efficacy of Lacosamide and Topiramate on Control of Neonatal Refractory Seizures

#### Protocol summary

##### Study aim

Comparison of the Safety and Efficacy of Lacosamide and Topiramate on Control of Neonatal Refractory Seizures

##### Design

A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 54 neonates with refractory seizure, using [www.sealedenvelope.com](http://www.sealedenvelope.com) for randomization.

##### Settings and conduct

This study was conducted in two centers, Ali Asghar and Firozabadi hospital. Neonates with refractory seizures were randomly assigned into two groups. In the first group, neonates received oral Lacosamide and in the second group, neonates received oral Topiramate. In this study, blinding was not done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Newborn with seizure who did not respond to phenobarbital (dose 20 mg/kg) and Levebel (40 mg/kg), Infants under 3 months with refractory seizures whose seizures have started since infancy (under one month), Seizures due to secondary abnormalities in asphyxia, brain structural disorders, familial seizures, congenital and acquired infections, vascular lesions. Exclusion criteria: Seizures that started after neonatal period, Seizures due to secondary abnormalities in metabolic disorders or electrolyte disorders.

##### Intervention groups

In the first intervention group infants receive Lacosamide tablets twice a day at a dosage of 2 mg/kg/day. In The second intervention group Infants receive Topiramate tablets twice a day at a dosage of 5 mg/kg/day.

##### Main outcome variables

Frequency of seizure

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230415057911N2**

Registration date: **2024-03-16, 1402/12/26**

Registration timing: **retrospective**

Last update: **2024-03-16, 1402/12/26**

Update count: **0**

##### Registration date

2024-03-16, 1402/12/26

#### Registrant information

##### Name

Mohammad Vafaeeshahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6253

##### Email address

vafaeeshahi.m@iums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2023-03-01, 1401/12/10

##### Expected recruitment end date

2024-01-30, 1402/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Comparison of the Safety and Efficacy of Lacosamide and Topiramate on Control of Neonatal Refractory Seizures

#### Public title

Efficacy of Lacosamide and Topiramate on Control of Neonatal Refractory Seizures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Neonates with seizure who did not respond to phenobarbital (dose 40 mg/kg) and Levetiracetam (40 mg/kg). Infants under 3 months with refractory seizures whose seizures have started since infancy (under one month). Seizures due to secondary abnormalities in asphyxia, brain structural disorders, familial seizures, congenital and acquired infections, vascular lesions

### Exclusion criteria:

Seizures that started after neonatal Period Seizures due to secondary abnormalities in metabolic disorders or electrolyte disorders.

## Age

From **1 day** old to **3 months** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **54**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The block randomization with block size of 4 and 6 used. generation of random sequence was done using [www.sealedenvelope.com](http://www.sealedenvelope.com) website. The random list were provided to an epidemiologist who had no involvement in selection of drug. Then subjects were randomly assigned into two groups of Lacosamide and Topiramate.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences; Next to the Milad Tower; Hemmat Highway

##### City

Tehran

## Province

Tehran

## Postal code

1449614535

## Approval date

2022-12-03, 1401/09/12

## Ethics committee reference number

IR.IUMS.FMD.REC.1401.689

## Health conditions studied

### 1

#### Description of health condition studied

Neonatal Seizure

#### ICD-10 code

P90

#### ICD-10 code description

Convulsions of newborn

## Primary outcomes

### 1

#### Description

The incidence of seizures

#### Timepoint

Before the intervention, 3 days and 7 days after the intervention

#### Method of measurement

Electroencephalography (EEG)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Infants receive Lacosamide tablets (manufactured by Dr. Abidi Company, Iran) twice a day at a dosage of 2 mg/kg/day. If no treatment response, 2 mg/kg is added to the previous dosage every 48 hours until the dose reaches 12 mg/kg, and if a neonate does not respond to the treatment within 48 hours after receiving dosage of 12 mg/kg, the drug is stopped.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Infants receive Topiramate tablets (manufactured by Aria Company, Iran) twice a day at a dose of 5 mg/kg/day. If no treatment response, 1 mg/kg is added to the previous dosage every 48 hours until we reach to dosage of 10 mg/kg, and if a neonate does not respond to the treatment until 48 hours after receiving the dose of 10 mg/kg, the drug is stopped. .

**Category**

Treatment - Drugs

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

Aliasghar Children's Hospital

**Full name of responsible person**

Mohammad Vafaeeshahi

**Street address**

No.193, Zafar St, Modares Highway.

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**2****Recruitment center****Name of recruitment center**

Firoozabadi Hospital

**Full name of responsible person**

Mohammad Vafaeeshahi

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak

**Street address**5th Floor of Setad Building, Next to the Milad Tower,  
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falak.r@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Vafaeeshahi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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

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**Person responsible for updating data**

**Contact**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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