

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 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 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.

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

vafaeeshahi.m@iums.ac.ir

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

Firoozabadi Hospital

Full name of responsible person

Mohammad Vafaeeshahi

Street addressBefore Shahr Ray Square; Fedayian Islam Street;
Shahr-e-Ray**City**

Tehran

Province

Tehran

Postal code

1849794113

Phone

+98 21 4055 6434

Email

vafaeeshahi.m@iums.ac.ir

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

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address5th Floor of Setad Building, Next to the Milad Tower,
Hemmat Highway.**City**

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

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

Street addressAli-e-Asghar Pediatric Hospital, No. 193, Modares
Highway, Zafar street**City**

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax**Email**

vafaeeshahi.m@iums.ac.ir

Person responsible for scientific 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

Street address

Ali-e-Asghar Pediatric Hospital, No. 193, Modares

Highway, Zafar street

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax

Email

vafaeshahi.m@iums.ac.ir

Highway, Zafar street

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax

Email

vafaeshahi.m@iums.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Vafaeshahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Ali-e-Asghar Pediatric Hospital, No. 193, Modares