Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 siezure, 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 (dose40 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.

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 the random list were provided to a epidemiologist who had no involvement to selection drug. Then subjects were randomly assigned into two groups of Locasamaid 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 address
Before 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 address
5th 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 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
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

vafaeeshahi.m@iums.ac.ir

Person responsible for updating data

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

vafaeeshahi.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