Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of phenobarbital, topiramate and levotiracetam in the treatment of neonatal seizure

Protocol summary

Study aim

Comparison of phenobarbital effects with topiramate and lutiracetam in the treatment of neonatal seizures. Comparison of the effect of phenobarbital with topiramate in neonatal seizure dermatitis. Comparison of the effect of phenobarbital with levothyracetan in neonatal seizure dermatitis. Comparison of the effect of topiramate with lutiracetam in neonatal seizure dermatitis.

Design

The research method is clinical practice with parallel groups, one-way blind and simple random

Settings and conduct

This research is performed by clinical practice in Tabriz Children's Hospital. The research is semi-experimental and one-way blind, and parents have no knowledge of drug comparisons.

Participants/Inclusion and exclusion criteria

Entry criteria: All infants who have been referred to a medical center due to seizures. Exclusion criteria: If factors other than seizures are seen in the baby.

Intervention groups

First, three groups of children with seizures will be randomly selected by computer randomization and 10-40 mg / kg / state and 5 mg / kg / day of bifurcation for one oral phenobarbital-based intervention group. Oral topiramate will be 3-8 mg / kg / day and for the third group, 10-40 mg / kg / day Lotirastam-based intervention will be performed.

Main outcome variables

Used the effect of drugs on the treatment of various types of seizures and reduce the number of seizures and the greater the effectiveness on seizure symptoms and effective treatment of seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046137N1**
Registration date: **2020-08-05, 1399/05/15**
Registration timing: **prospective**

Last update: **2020-08-05, 1399/05/15**
Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Shahram Sadeghvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2280

Email address

sadeghvandsh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of phenobarbital, topiramate and levotiracetam in the treatment of neonatal seizure

Public title

The effect of phenobarbital, topiramate, and levothiracetam on neonatal seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All infants who had seizures after birth

Exclusion criteria:

Babies who were hospitalized for other reasons, such as apnea or thrush

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

From the simple random method and the sequential assignment of each newborn to a group of drugs, this simple random method will continue for each group of 20 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher is aware of the division of groups, and the parents have received explanations about the research, but they are not aware of the division of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Daneshgah street, Ethics Committee of Tabriz University of Medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5157664988

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.TBZMED.REC.1398.1071

Health conditions studied

1

Description of health condition studied

Neonatal seizures

ICD-10 code

P90

ICD-10 code description

Convulsions of newborn

Primary outcomes

1

Description

Seizure type

Timepoint

Every month

Method of measurement

Clinical history

2

Description

Frequent seizures

Timepoint

Every month

Method of measurement

Clinical history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Phenobarbital 15mg tablet of Hayan Company with a dose of 5mg / kg / day / bid

Category

Treatment - Drugs

2

Description

Oral Topiramate tablets 25 mg by Hayan Company with a dose of 3 mg / kg / day / bid

Category

Treatment - Drugs

3

Description

Oral Lothirastam Syrup 100 mg / Hayan Company with a dose of 20 mg / kg / day / bid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr. Mir Hadi Mousavi

Street address

Sheshgelan Street, Tabriz Children Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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Daneshgah Street, Research Vice-Chancellor of Tabriz university of Medical Sciences

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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

Tabriz University of Medical Sciences

Proportion provided by this source

10

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Leila Islamian Ghadim

Position

Children's resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Children Hospital, Seshghelaan St., Seggat ol Eslam Ave.

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Person responsible for scientific inquiries

Contact

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Position

Pediatric neurologist

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
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Other areas of specialty/work
Pediatrics

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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
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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Use of medical findings and reputable scientific journals

When the data will become available and for how long
June 2021

To whom data/document is available
Instructors and medical journals

Under which criteria data/document could be used
For practical, therapeutic and scientific use

From where data/document is obtainable
Research Vice Chancellor of Tabriz University of Medical Sciences and reputable publications

What processes are involved for a request to access data/document
By email and correspondence

Comments