

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

efficacy of Levetiracetam compared to intravenous Phenytoin in treatment of acute phase of neonatal seizure

Protocol summary

Study aim

1) determination and Comparison of the efficacy of levetiracetam and intravenous phenytoin in the treatment of the acute phase of neonatal seizures

Design

A parallel-group, phase 3 clinical trial on 60 infants.
Randomization by random numbers

Settings and conduct

Patients admitted to the neonatal and neonatal intensive care unit of Shahid Motahari hospital in Urmia, who were diagnosed with neonatal convulsions, will be included in the study in a period of six months from October 1401 to March 1401. Patients admitted on this date will be numbered from 1 to 60 in order of admission date. Then according to the patient number and treatment group, the babies will be treated with a medicine. The prescribed dose of each drug for patients will be 20 mg per kilogram of body weight per day as a single dose and slow intravenous injection over a period of 5 to 15 minutes. The response to the treatment will be defined as seizure control and non-recurrence within 24 hours after drug injection. In case of lack of control, patients will be treated with phenobarbital at the rate of 20 mg per kilogram of body weight. Patient information such as gestational age, birth weight, gender, delivery method (natural and cesarean section), pregnancy problems (diabetes, blood pressure, IUGR, asphyxia), type of seizures will be collected and recorded from the patient files. The rate of response to treatment with one dose of medicine will also be recorded. The information will be analyzed by SPSS version 21 software.

Participants/Inclusion and exclusion criteria

neonate with seizure

Intervention groups

1)Levetiracetam 2) Phenytoin

Main outcome variables

Efficacy of phenytoin and levetiracetam in the treatment of neonatal seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220619055221N1**

Registration date: **2022-11-09, 1401/08/18**

Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**

Update count: **0**

Registration date

2022-11-09, 1401/08/18

Registrant information

Name

Parvaneh Babaey sisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3224 1967

Email address

parvanehbabaey@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy of Levetiracetam compared to intravenous Phenytoin in treatment of acute phase of neonatal seizure

Public title

Comparing the effects of levetiracetam and phenytoin in the treatment of neonatal seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

neonate with seizure term neonate up to 28 days
preterm neonate up to 44 weeks of gestational age

Exclusion criteria:

neonate without seizure

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

in this study, the block randomization method will be used, so that at first all the possible states of the combination AAABBB will be listed, then according to the sample size (60) and the block size equal to 6, 10 blocks will be randomly selected. will be selected. The selection of randomization will be such that first all possible combinations of 6 will be listed and a code will be assigned for each, and then 10 blocks will be selected and listed in order, and the allocation of people will be based on this list. The codes will be secret and only available to the epidemiological consultant. All steps will be done under the supervision of an epidemiologist and using Random Allocation software, version one.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the intervention, the participants, the researcher and the outcome evaluator do not know the type of intervention and it will only be based on the codes that will be available to an independent person as an observer to take action in case of possible complications and problems.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Urmia
University of Medical Sciences, Resalat St

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSU.REC.1401.276

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

Efficacy of phenytoin and levetiracetam in the treatment of neonatal seizures

Timepoint

The first 24 hours after the drug

Method of measurement

No recurrence of seizures in the first 24 hours after the drug

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Levetiracetam Dose 20 mg/kg starting and continuing to 10 mg/kg

Category

Treatment - Drugs

2

Description

Intervention group: Phenytoin Dose 20 mg/kg starting and continuing to 3-5 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Neonatal and Neonatal Special Care,
Shahid Motahari Hospital, Urmia

Full name of responsible person

Parvaneh Babaey Sisi

Street address

Kashani St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences Research Vice
President

Full name of responsible person

Parvaneh Babaey Sisi

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NO.51 , 13 Kashani St

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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

Urmia University of Medical Sciences Research Vice
President

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

Oroumia University of Medical Sciences

Full name of responsible person

Parvaneh Babaey Sisi

Position

Children's assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Alireza abdi

Position

Specialist in pediatric neurology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

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

Information about the infant and the horse's anticonvulsant treatment can be shared.

When the data will become available and for how long

It is possible to start the access period 6 months after the publication of the study results.

To whom data/document is available

Researchers in the institutions of universities of medical sciences can apply for them.

Under which criteria data/document could be used

After sending the email, it will be possible to access the data.

From where data/document is obtainable

Dr. Aireza Abdi alireza.abdi129@gmail.com

What processes are involved for a request to access data/document

6 months after printing the results, send an email confirming the request so that the requested data can be sent.

Comments