

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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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West Azarbaijan

**Postal code**

57661715335

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+98 914 882 4826

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parvanehbabaey@gmail.com

**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

**Street address**

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

**Street address**

No.2 ,shahrdari st, Sis

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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**

Neurology

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Kashani st

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## Person responsible for updating data

### 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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## 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**