

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the therapeutic efficacy of intravenous Levetiracetam and phenobarbital as first-line treatment for neonatal seizures

Protocol summary

Study aim

Comparing the therapeutic efficacy of intravenous Levetiracetam (Matever) and phenobarbital as first-line treatment for neonatal seizures in Bahrami Hospital

Design

A Block-randomized, double-blinded controlled clinical trial on 44 neonates

Settings and conduct

Neonates, either term or preterm, with neonatal seizure manifestations who were referred to Bahrami Hospital in Tehran between 2019-2020 were included in this study. Patients were randomly categorized into two groups, one receiving Phenobarbital and the other Levetiracetam as the initial seizure management medication. Seizure control and prevention of seizure repeats were compared between the two groups in 48 hours. Informed consent was obtained from the patients' parents or legal guardians.

Participants/Inclusion and exclusion criteria

Neonates with neonatal seizure manifestations were included in this study. Patients with hepatic dysfunction; renal dysfunction; or lack of consent were excluded.

Intervention groups

Administration of intravenous levetiracetam as the first-line medication for neonatal seizure control and prevention of seizure recurrence within 48 hours. Intravenous form of phenobarbital was used for the control group.

Main outcome variables

seizure control comparison Prevention of seizure repeats comparison

General information

Reason for update

Acronym

LPNS

IRCT registration information

IRCT registration number: **IRCT20220410054471N1**

Registration date: **2023-07-26, 1402/05/04**

Registration timing: **retrospective**

Last update: **2023-07-26, 1402/05/04**

Update count: **0**

Registration date

2023-07-26, 1402/05/04

Registrant information

Name

kamyar kamrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2292 1930

Email address

k_kamrani@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2021-03-20, 1399/12/30

Trial completion date

2021-03-20, 1399/12/30

Scientific title

Comparing the therapeutic efficacy of intravenous Levetiracetam and phenobarbital as first-line treatment for neonatal seizures

Public title

Comparing Levetiracetam and phenobarbital as first-line

treatment for neonatal seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with seizure manifestations

Exclusion criteria:

Renal impairment Lack of consent

Age

To **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using the block randomization technique using 4 and 6 allele blocks. Using blocks consisting of A, and B alleles, 4- and 6-allele structures like AAAA, and ABBA, etc. were formed and were randomly allocated to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects of this study are neonates; thus they do not know which group they are being allocated to, and moreover, the researcher does not know which neonate is receiving which drug. As a result, this study can be considered double blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods Ave. crossing, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-11-14, 1399/08/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.747

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

seizure control

Timepoint

48 hours

Method of measurement

clinical

2

Description

seizure recurrence control

Timepoint

48 hours

Method of measurement

Clinical

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bolus Intravenous Levetiracetam (Matever) with a 20 mg/kg dose as initial therapy

Category

Treatment - Drugs

2

Description

Control group: Bolus Intravenous phenobarbital with a 20 mg/kg dose as initial therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Hospita;

Full name of responsible person

Kamyar Kamrani

Street address

Kiani Str., Damavand Ave., Emam Hossein sqr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Qods Ave. Crossing, Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Kamyar Kamrani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

In this study, data will be sharable after making it anonymous, upon request

When the data will become available and for how long

Data can be shared, 3 months following publication upon request

To whom data/document is available

University and research centers researchers can use the shared data

Under which criteria data/document could be used

The data will be shared with researchers for research and academic purposes.

From where data/document is obtainable

Access to data will be through the correspondent author by email communication

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

Following submission for access to data, according to the correspondent judgment, the request will be assessed in a research team meeting, and if accepted, the data will be presented after becoming anonymous.

Comments