

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Clinical trial of comparison of intravenous Levetiracetam and phenobarbital for first line treatment of acute neonatal seizures

Protocol summary

Study aim

The aim of this study is comparison of intravenous Levetiracetam and phenobarbital for first line treatment of acute neonatal seizures

Design

The study design is clinical trial with control group, with parallel groups, not blinded and simple randomization method and patients will be studied in two groups of 25 cases.

Settings and conduct

In this not-blinded clinical trial, all neonates admitted to the neonatal intensive care unit of BuAli hospital of Sari due to seizure are evaluated.

Participants/Inclusion and exclusion criteria

Term neonates with age \leq 28 days, clinical seizures requiring treatment based on the diagnosis of a neonatologist or pediatric neurologist and obtaining written informed consent of parents are included

Intervention groups

In the intervention group, Levetiracetam made by Estragen Company, Switzerland with initial loading dose of 30 mg/kg with slow intravenous infusion is applied for 15 minutes and 10 mg/kg maintenance dose is used for 12 hours diluted with normal saline. In the control group, Phenobarbital made by Pars Daroo company is injected with loading dose of 20 mg/kg, which is increased upto 40 mg/kg if seizure is not controlled.

Main outcome variables

The main outcomes of the study include seizures, frequency of seizures, drug side effects, and intervention outcome (seizure control in 30 minutes).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090412001808N7**

Registration date: **2020-01-24, 1398/11/04**

Registration timing: **retrospective**

Last update: **2020-01-24, 1398/11/04**

Update count: **0**

Registration date

2020-01-24, 1398/11/04

Registrant information

Name

Ali Abbaskhanian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1223 3010

Email address

aabbaskhanian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

2018-06-21, 1397/03/31

Actual recruitment end date

2019-05-21, 1398/02/31

Trial completion date

2019-06-22, 1398/04/01

Scientific title

Clinical trial of comparison of intravenous Levetiracetam and phenobarbital for first line treatment of acute neonatal seizures

Public title

The effect of Levetiracetam and phenobarbital in

treatment of neonatal seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term neonates Age \leq 28 days Clinical seizures requiring treatment based on the diagnosis of a neonatologist Seizure diagnosis based on pediatric neurologist diagnosis and EEG interpretation Written informed consent of parents

Exclusion criteria:

Renal failure Seizures caused by electrolyte disorders such as hypocalcemia and hypoglycemia Patients whose seizures respond to vitamin B6 administration Sensitivity to Levetiracetam or phenobarbital Structure Anomaly Asphyxia

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.

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 Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.MAZUMS.REC.1398.543

Health conditions studied

1

Description of health condition studied

Acute neonatal seizure

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Seizure

Timepoint

30 min, 24 hour up to 1 week, 1st month, 2nd month, 3rd month

Method of measurement

Clinical examination and observation of paroxysmal movements of the neonate

Secondary outcomes

1

Description

Seizure recurrence

Timepoint

30 min, 24 hour up to 1 week, 1st month, 2nd month, 3rd month

Method of measurement

Clinical examination and observation

Intervention groups

1

Description

Intervention group: Levetiracetam made by Estragen Company, Switzerland with initial loading dose of 30 mg/kg with slow intravenous infusion is injected for 15 minutes and maintenance dose of 10 mg/kg for 12 hours diluted with normal saline. If the seizure is controlled, the injectable drug will gradually decrease and become orally administered at a maintenance dose of 5 mg/kg/day.

Category

Treatment - Drugs

2

Description

Control group: Phenobarbital drug produced by Pars Darou Company is injected at a loading dose of 20 mg/kg which can be increased up to 40 mg/kg if seizure is not controlled. If the seizure is stopped, the injectable drug will gradually decrease and become orally administered at a maintenance dose of 5 mg/kg/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Bouli hospital of Sari

Full name of responsible person

Dr. Ali Abbaskhanian

Street address

Buali Hospital, Pasdaran Boulevard, Sari, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem square, Sari

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ali Abbaskhanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Ali Abbaskhanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Nayyerolsadat Tahami

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Pediatric Assistant

Latest degree

Specialist

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data is shareable after people are unrecognizable

When the data will become available and for how long

Starting from April 2020

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

The data will be used for research and surveillance purposes, with the confidentiality of individuals' personal information

From where data/document is obtainable

Send email to Dr. Ali Abbaskhanian, snali45@yahoo.com

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

Written Request from Research Deputy of Mazandaran University of Medical Sciences and Dr. Abbaskhanian

Comments