

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the outcomes of neonatal seizure treatment with phenobarbital versus levetiracetam after discharge

Protocol summary

Study aim

Comparison of the outcomes of neonatal seizure treatment with phenobarbital versus levetiracetam after discharge

Design

Clinical trial with control and parallel groups, double blind, randomized

Settings and conduct

This study will be performed on 60 infants with a gestational age of more than 36 weeks who were admitted to the neonatal intensive care unit of Ghaem Hospital due to seizures. Patients are randomly divided into two groups and at the time of discharge, one group is treated with phenobarbital and the other with levetiracetam. In this double-blind study, patients and outcome assessors are unaware of the type of grouping. Patients are evaluated for recurrence of seizures and growth and development at the time of discharge and also three and six months after discharge.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The age when seizures started is less than one month; history of at least one seizure with an unknown cause; need for treatment at the time of discharge based on history, type of seizure and EEG. Exclusion criteria: Finding any errors of metabolism as the cause of seizures; finding any structural abnormalities in the brain on magnetic resonance imaging of the brain or head ultrasound; gestational age is below 36 weeks; congenital metabolic disorders

Intervention groups

Intervention group: Patients are treated with 30 mg/kg levetiracetam. Control group: Patients are treated with 5 mg/kg phenobarbital.

Main outcome variables

Reoccurrence of seizures; newborn's growth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200131046317N3**

Registration date: **2021-08-25, 1400/06/03**

Registration timing: **prospective**

Last update: **2021-08-25, 1400/06/03**

Update count: **0**

Registration date

2021-08-25, 1400/06/03

Registrant information

Name

Javad Akhondian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 7451

Email address

akhondianj@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-06-11, 1401/03/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcomes of neonatal seizure treatment with phenobarbital versus levetiracetam after discharge

Public title

Comparison of the effects of phenobarbital and levetiracetam on neonatal seizure after discharge

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age when seizures started is less than one month

History of at least one seizure with an unknown cause

Need for treatment at the time of discharge based on history, type of seizure and EEG

Exclusion criteria:

Finding any errors of metabolism as the cause of

seizures Gestational age is below 36 weeks Congenital

metabolic disorders Finding any structural abnormalities

in the brain on magnetic resonance imaging of the brain or head ultrasound

Age

From **1 day** old to **1 month** 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

The envelopes will be prepared by one of the members of the research team and the random numbers generated by the "www.randomization.com" website will be printed and placed in each envelope. The envelopes are sealed and their contents are not visible from outside. At first, purpose of the study is explained for each participants and after filling out the consent form, each participant selects an envelope and opens it and based on its content, the participant will be placed in either control or intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not aware of the type of treatment and the intervention. Also, outcome assessors are unaware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.208

Health conditions studied

1

Description of health condition studied

convulsion of newborn

ICD-10 code

P90

ICD-10 code description

Convulsions of newborn

Primary outcomes

1

Description

reoccurrence of seizures

Timepoint

3 and 6 months after discharge

Method of measurement

Based on parents' reports

2

Description

the newborn's growth

Timepoint

3 and 6 months after discharge

Method of measurement

Clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated with 30 mg/kg levetiracetam daily after discharge and

are followed for recurrence of seizures, complications and neonatal development 3 and 6 months after discharge. The duration of treatment will be decided based on examinations and EEG.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group are treated with 5 mg/kg phenobarbital daily after discharge and are followed for recurrence of seizures, complications and neonatal development 3 and 6 months after discharge. The duration of treatment will be decided based on examinations and EEG.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Nazanin Saeidi Zand

Street address

Ghaem hospital, Ahmad Abad Ave.

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Postal code

9176699199

Phone

+98 51 3801 2649

Email

dr.nazanin_zand@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Nazanin Saeidi Zand

Position

Student of sub specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Javad Akhondian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Nazanin Saeidi Zand

Position

Student of sub specialist

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

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible through an email to the corresponding author.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Data can be accessible 6 months after results are published.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Carrying out analysis on data is permitted.

Comments