Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy and safety of Levetiracetam and Phenobarbital in controlling neonatal seizures

Protocol summary

Study aim
Comparison of efficacy and safety of levetiracetam and phenobarbital in controlling neonatal seizures

Design
A clinical trial with a control group with a parallel-group design, double-blind; randomized; Phase 2-3, on 40 patients. Block randomization method will be used for randomization.

Settings and conduct
The design will be a double-blinded controlled clinical trial (Parents of infants and the person who fills out the questionnaires) which is due to the uniform form of the drug which will be done in the NICU of Besat Hospital in Hamadan in 2022. Infants under 1 month of age with a gestational age of 36 weeks admitted to the NICU due to seizures are included in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age of 36 weeks or more; Weighing 2 kg or more; Occurrence of neonatal seizures between the first day and the 28th day after birth; Consent of the baby's parents or legal guardian.
Exclusion criteria: Receiving anti convulsion drugs in the last 72 hours; Seizures due to hypocalcemia, hypoglycemia, hypomagnesemia, and other electrolyte disorders; Serum creatinine level greater than 1.6 mg / dL

Intervention groups
Intervention group: The patients are treated with levetiracetam injection (500 mg / 5ml, produced by STRAGEN pharmaceutical company) at a loading dose of 50 mg/kg and infusion rate of 2 mg/kg/min (within 10 Cc of normal saline) under cardiorespiratory monitoring.
Control group: Patients are treated with Phenobarbital injection (200mg/ml, produced by Chemidarou company) at a loading dose of 20 mg/kg and at an infusion rate of 1 m/kg/min (within 10 Cc of normal saline) under cardiorespiratory monitoring.

Main outcome variables
No seizures for 24 hours after medication; Number of doses received to stop seizures; Side effects such as irritability and anorexia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N23**
Registration date: **2022-06-13, 1401/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-13, 1401/03/23**
Update count: **0**

Registration date
2022-06-13, 1401/03/23

Registrant information

Name
Mohammad Faryadras

Name of organization / entity
Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-05, 1401/02/15

Expected recruitment end date
2022-07-06, 1401/04/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of Levetiracetam and Phenobarbital in controlling neonatal seizures

Public title

The effect of levetiracetam and phenobarbital on the control of neonatal seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age of 36 weeks or more Weighing 2 kg or more Occurrence of neonatal seizures between the first day and the 28th day after birth Consent of the baby's parents or legal guardian

Exclusion criteria:

Receiving anti convulsion drugs in the last 72 hours Seizures due to hypocalcemia, hypoglycemia, hypomagnesemia, and other electrolyte disorders Serum creatinine level greater than 1.6 mg / dL

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups based on a table of random numbers. A random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and become a table. In order to use a random number table, the researcher must first predetermine the table to read the numbers for example, up, down, left, or right. Individuals receive a number based on the order of enrollment. Individual numbers are assigned to patients in the intervention group and even numbers are assigned to patients in the control group. assumption.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to randomization, the patient is assigned to one of the control or intervention groups. Drugs that have the same shape are prepared in the ward, drawn in a syringe, and then administered at the patient's bedside. Thus, the form of drug administration will be the same in both groups; based on it, the type of drug can not be determined. Parents of infants and the person who fills out the questionnaires will not know about the prescribed medicine and the form will be filled in according to the assigned code.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmide street

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.UMSHA.REC.1399.681

Health conditions studied

1

Description of health condition studied

Convulsions of newborn

ICD-10 code

P90

ICD-10 code description

Convulsions of newborn

Primary outcomes

1

Description

Complete cessation of seizures for 24 hours after medication

Timepoint

In the first 24 hours after medication

Method of measurement

Stopping seizure movements clinically (clinical assessment)

2

Description

Number of doses received to stop seizures

Timepoint

In the first 24 hours after medication

Method of measurement

Patient medical record

Secondary outcomes

1

Description

Reduce irritability

Timepoint

Before and after intervention

Method of measurement

Daily clinical examination and parental observations

2

Description

Reduce anorexia

Timepoint

Before and after intervention

Method of measurement

Daily clinical examination and parental observations

Intervention groups

1

Description

Intervention group: Patients are treated with levetiracetam injection (500 mg / 5ml by Estragen Company, Switzerland) at a loading dose of 50 mg/kg and infusion rate of 2 mg/kg/min (within 10 Cc of normal saline) under cardiorespiratory monitoring. If seizures continue with the first dose of levetiracetam, the drug is re-loaded at a dose of 50 mg/kg by the same infusion rate (within 10 cc of normal saline). If the seizure does not stop or returns after 15 minutes, even after the second dose of medication, the treatment groups are changed. If the seizure does not stop or returns after 15 minutes after changing treatment groups, other anticonvulsant drugs are used.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group are treated with Phenobarbital injection (200mg/ml from Chemidarou company) at a loading dose of 20 mg/kg and at an infusion rate of 1 m/kg/min (within 10 Cc of normal saline) under cardiorespiratory monitoring,If the seizure continues with the first dose, phenobarbital is re-loaded by infusion at a dose of 20 mg per kg at the same rate as before. If the seizure does not stop or returns after 15 minutes, even after the second dose of medication, the treatment groups are changed. If the seizure does not stop or returns after 15 minutes after changing treatment groups, other anticonvulsant drugs are used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Nader Faraji

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Fatemi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nader Faraji

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available