# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

**Country**
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**

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**Province**

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**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

**Street address**

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**

Reza Shokohei

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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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## Person responsible for updating data

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**Position**

Neonatologist- assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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