Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

efficacy of Levetiracetam compared to intravenous Phenytoin in treatment of acute phase of neonatal seizure

Protocol summary

Study aim
1) determination and Comparison of the efficacy of levetiracetam and intravenous phenytoin in the treatment of the acute phase of neonatal seizures

Design
A parallel-group, phase 3 clinical trial on 60 infants. Randomization by random numbers

Settings and conduct
Patients admitted to the neonatal and neonatal intensive care unit of Shahid Motahari hospital in Urmia, who were diagnosed with neonatal convulsions, will be included in the study in a period of six months from October 1401 to March 1401. Patients admitted on this date will be numbered from 1 to 60 in order of admission date. Then according to the patient number and treatment group, the babies will be treated with a medicine. The prescribed dose of each drug for patients will be 20 mg per kilogram of body weight per day as a single dose and slow intravenous injection over a period of 5 to 15 minutes. The response to the treatment will be defined as seizure control and non-recurrence within 24 hours after drug injection. In case of lack of control, patients will be treated with phenobarbital at the rate of 20 mg per kilogram of body weight. Patient information such as gestational age, birth weight, gender, delivery method (natural and cesarean section), pregnancy problems (diabetes, blood pressure, IUGR, asphyxia), type of seizures will be collected and recorded from the patient files. The rate of response to treatment with one dose of medicine will also be recorded. The information will be analyzed by SPSS version 21 software.

Participants/Inclusion and exclusion criteria
neonate with seizure

Intervention groups
1)Levetiracetam 2) Phenytoin

Main outcome variables
Efficacy of phenytoin and levetiracetam in the treatment of neonatal seizures

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220619055221N1**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**

Registration date
2022-11-09, 1401/08/18

Registrant information
Name
Parvaneh Babaey sisi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 44 3224 1967
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parvanehbabaey@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

efficacy of Levetiracetam compared to intravenous Phenytoin in treatment of acute phase of neonatal seizure

Public title
Comparing the effects of levetiracetam and phenytoin in the treatment of neonatal seizures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
neonate with seizure term neonate up to 28 days preterm neonate up to 44 weeks of gestational age
Exclusion criteria:
neonate without seizure
Age
From **1 day** old to **28 days** 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
in this study, the block randomization method will be used, so that at first all the possible states of the combination AAABBB will be listed, then according to the sample size (60) and the block size equal to 6, 10 blocks will be randomly selected. will be selected. The selection of randomization will be such that first all possible combinations of 6 will be listed and a code will be assigned for each, and then 10 blocks will be selected and listed in order, and the allocation of people will be based on this list. The codes will be secret and only available to the epidemiological consultant. All steps will be done under the supervision of an epidemiologist and using Random Allocation software, version one.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the nature of the intervention, the participants, the researcher and the outcome evaluator do not know the type of intervention and it will only be based on the codes that will be available to an independent person as an observer to take action in case of possible complications and problems.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Urmia University of Medical Sciences, Resalat St
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2022-10-22, 1401/07/30
Ethics committee reference number
IR.UMSU.REC.1401.276

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
Efficacy of phenytoin and levetiracetam in the treatment of neonatal seizures
Timepoint
The first 24 hours after the drug
Method of measurement
No recurrence of seizures in the first 24 hours after the drug

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Levetiracetam Dose 20 mg/kg starting and continuing to 10 mg/kg
Category
Treatment - Drugs

2

Description
Intervention group: Phenytoin Dose 20 mg/kg starting and continuing to 3-5 mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Neonatal and Neonatal Special Care, Shahid Motahari Hospital, Urmia
Full name of responsible person
Parvaneh Babaey Sisi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences Research Vice President
Full name of responsible person
Parvaneh Babaey Sisi
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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
Urmia University of Medical Sciences Research Vice President
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
Oroumia University of Medical Sciences
Full name of responsible person
Parvaneh Babaey Sisi
Position
Children's assistant
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
Information about the infant and the horse's anticonvulsant treatment can be shared.

When the data will become available and for how long
It is possible to start the access period 6 months after the publication of the study results.

To whom data/document is available
Researchers in the institutions of universities of medical sciences can apply for them.

Under which criteria data/document could be used
After sending the email, it will be possible to access the data.

From where data/document is obtainable
Dr. Aireza Abdi alireza.abdi129@gmail.com

What processes are involved for a request to access data/document
6 months after printing the results, send an email confirming the request so that the requested data can be sent.

Comments