Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of intravenous levetiracetam and phenobarbital for management of neonatal seizures

Protocol summary

Study aim
The aim of this study was to examine the efficacy of intravenous levetiracetam compared to oral Phenobarbital in a randomized clinical trial.
Design
Randomized Clinical trial using blocking methods with 50 individuals in each group, Two-sided blinding
Settings and conduct
legal guardianship and investigator of intervention results will ba blind
Participants/Inclusion and exclusion criteria
Infants with acute seizures need treatment with seizure management
Intervention groups
intravenous levetiracetam
Main outcome variables
Seizure, Count of Recurrent, drug side effects, treatment results

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190526043717N1**
Registration date: **2019-05-31, 1398/03/10**
Registration timing: **prospective**

Last update: **2019-05-31, 1398/03/10**
Update count: **0**
Registration date
2019-05-31, 1398/03/10

Registrant information
Name
Mansoureh Safari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-06-10, 1398/03/20
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of intravenous levetiracetam and phenobarbital for management of neonatal seizures

Public title
Comparison of intravenous levetiracetam and phenobarbital in neonatal seizures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
require for neonatal seizures management Weight > 2500gr birth age>37 weaks Individuals without renal dysfunction Individuals without dysfunction of the immune system
Exclusion criteria:
Healthy individuals Weight <2500 gr Birth age <37 weaks renal dysfunction immune system dysfunction
Age
From **1 day** old to **12 months** old
Gender

Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining informed consent, the random blocking method with a size of 4 will be allocated to each of the two treatment groups. Blocks will be determined randomly and using the PROC PLAN method in SAS 9.3 software by a biostatistician for the person who enters the study into the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
legal guardianship, as well as the investigator who measures the events related to intervention, will not be aware of the type of treatments, the coding method will be used to provide intervention, the code breaks will be available to the researcher after measuring the consequences as well as analysis of the results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
IR-MUQ-REC
Street address
saheli
City
qom
Province
Ghoum
Postal code
3713649373
Approval date
2019-03-05, 1397/12/14
Ethics committee reference number
1397.210.IR.MUQ.REC

Health conditions studied

1

Description of health condition studied
Neonatal Seizures
ICD-10 code
G40
ICD-10 code description
Epilepsy and recurrent seizures

Primary outcomes

1

Description
seizures
Timepoint
30 min, 24 h up to 1 w, 1th m, 2th m, 3th m
Method of measurement
clinical observation

Secondary outcomes

1

Description
neonatal seizures recurrence
Timepoint
24 h up to 1 weak, first month, two month, and three month after intervention
Method of measurement
clinical observation

Intervention groups

1

Description
Intervention group: Levetiracetam intravenous 20-40 mg/kg/day, 15mg/kg/day per 12 h
Category
Treatment - Drugs

2

Description
Control group: Phenobarbital 20mg/kg two time a day, increasing dose up to 30mg/kg during 3 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrateh Masoumeh hospital
Full name of responsible person
Dr. Alireza Sadati

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Emam
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3719815539
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Dr. Hossein Sagafi
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Alireza Sadati
Position
Associate professor
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Person responsible for updating data

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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 additional information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The summarize information of samples will be published, so individual information remains secret.

When the data will become available and for how long

After 2019

To whom data/document is available

The ethics committee assessment team of Qom University of Medical Sciences

Under which criteria data/document could be used

For research aims as well as data quality assessment with considering the encoded information at the individual levels

From where data/document is obtainable

Dr. Alireza Saadati, Qom University of Medical Sciences, Qom, Iran a-saadati md@yahoo.com

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

Data Request Letter to the deputy of Research of Qom University of Medical Sciences and Dr. Alireza Saadati

Comments