

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The efficacy of intravenous phenobarbital as once or twice daily dose in neonates with seizure in NICU

Protocol summary

Study aim

Comparison of phenobarbital efficiency either single or twice daily regimens in the treatment of neonatal seizures

Design

This study was a double-blind randomized clinical trial (phase 3) with parallel groups. By simple randomization method, 24 patients who met the inclusion criteria and completed the informed consent were divided into two groups. Random number generation software (using www.random.org) determined a number for each patient, if the number was odd, the patient was assigned to group 1 and if it was even, the patient was assigned to group 2. The randomization process was performed by the ward head nurse (who was independent of the main researchers) when the patient entered the study and the intervention was assigned according to his group therapy.

Settings and conduct

This study was conducted in Sari Bu-Ali Sina hospital. Due to the different ways of using phenobarbital, we were able to blind only the outcome assessor and data analyst to the study groups. The randomization process was performed by the ward supervisor who was independent of the principal investigators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The infants with seizure who received phenobarbital
Exclusion criteria: Having liver or kidney diseases

Intervention groups

Group 1 (once daily): They received intravenous (IV) phenobarbital with an initial dose of 20 mg/kg and as needed with an increase of 10 mg/kg every 15 minutes to a maximum of 40 mg/kg and a maintenance dose of 5 mg/kg/day for 5 days. Group 2 (twice daily): They received IV phenobarbital with an initial dose of 20 mg/kg and, if necessary, an increase of 10 mg/kg every 15 minutes up to a maximum of 40 mg/kg, followed by a dose of 2.5 mg/kg every 12 hours for 5 days. All of

phenobarbital ampules (200 mg/ml) were prepared from Darou Pakhsh Co, Iran.

Main outcome variables

1) Phenobarbital plasma concentration
2) The numbers of new seizure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090813002342N12**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **retrospective**

Last update: **2020-12-31, 1399/10/11**

Update count: **0**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Mohammad Reza Rafati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-11-21, 1397/08/30

Scientific title

The efficacy of intravenous phenobarbital as once or twice daily dose in neonates with seizure in NICU

Public title

Once or twice daily dose of phenobarbital to control seizure in neonates

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Newborns with seizures that use IV phenobarbital

Exclusion criteria:

Neonates with liver or kidney failure

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple randomization method, patients who met the inclusion criteria and completed informed consent were assigned to two groups. Random number generation software (using www.random.org) determined a number for each patient, if the number was odd, the patient was assigned to group 1 and if it was even, the patient was assigned to group 2. The randomization process was performed by the ward supervisor (who was independent of the principal investigators). Randomization was performed when the patient entered the study and the intervention was assigned according to his group therapy.

Blinding (investigator's opinion)

Double blinded

Blinding description

If phenobarbital was prescribed for a baby due to seizures, it was written by the treating physician and the trained head nurse placed the baby in group 1 or 2 according to a random code obtained from www.random.org (odd or even). Due to the different ways of using phenobarbital, we were able to blind only the outcome assessor and data analyst to the study groups. All patients received intravenous phenobarbital with an initial dose of 20 mg / kg and, if necessary, increased by 10 mg / kg every 5 minutes to a maximum

of 40 mg / kg. Then, group 1 patients received a single maintenance dose of 5 mg / kg. The daily dose and group 2 patients also received 5.2 mg / kg every 12 hours.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Science

Street address

Payambar Azam Complex, 18 Km Farah Abad Blvd., Sari, Mazandaran Province

City

Sari

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Mazandaran

Postal code

4815733971

Approval date

2017-05-24, 1396/03/03

Ethics committee reference number

IR.MAZUMS.REC.1396.3133

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**

Phenobarbital plasma concentration

Timepoint

Before starting the phenobarbital maintenance dose and at third day of maintenance therapy

Method of measurement

by High Performance Liquid Chromatography

Secondary outcomes

1

Description

The numbers of new seizurs

Timepoint

During the study time for 5 days

Method of measurement

The visual report of responsible doctor or nurse

Intervention groups

1

Description

Group 1 (once daily): Patients were received intravenous (IV) phenobarbital with an initial dose of 20 mg/kg and as needed with an increase of 10 mg/kg every 15 minutes to a maximum of 40 mg/kg and a maintenance dose of 5 mg/kg/day for 5 days. All of phenobarbital ampules (200 mg/ml) were prepared from Darou Pakhsh Co. Iran. Drug was administered at a maximum rate of 1 mg/kg/min as intravenous infusion.

Category

Treatment - Drugs

2

Description

Group 2 (twice daily): Patients were received IV phenobarbital with an initial dose of 20 mg/kg and, if necessary, an increase of 10 mg/kg every 15 minutes up to a maximum of 40 mg/kg, followed by a dose of 2.5 mg/kg every 12 hours for 5 days. The first maintenance dose was used 12 hours after the loading dose. All of phenobarbital ampules (200 mg/ml) were prepared from Darou Pakhsh Co. Iran. Drug was administered at a maximum rate of 1 mg/kg/min intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina hospital

Full name of responsible person

Vajihe Ghaffari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammadreza Rafati

Position

Associate Professor of Clinical Pharmacy

Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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