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

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1354 3083

Email address

mrrafati@mazums.ac.ir

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
Province
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
Street address
Bu-Ali Sina Hospital, Pasdaran Blvd., Sari, Mazandaran, Iran
City
SARI
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 3014
Email
vghaffari@yhoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Mazandaran University of Medical Sciences, Deputy of Research and Technology, Moallem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3448 4800
Email
majsaeedi@yahoo.com
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
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran

Postal code
4847116548
Phone
+98 11 3354 3081
Email
mrrafati@mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mohammadreza Rafati
Position
Associate Professor of Pediatrics
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Bu-Ali Sina Hospital, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 3014
Email
vghaffari@yahoo.com

Person responsible for updating data

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
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
Postal code
4847116548
Phone
+98 11 3354 3081
Email
mrrafati@mazums.ac.ir

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