

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of phenobarbital on the outcome of early ischemic encephalopathy Hypoxemic

Protocol summary

Summary

Introduction: the effect of early administration of phenobarbital on the outcome Hpyvksyk ischemic encephalopathy, single-center, phase three trials, single-center, phase 3 trial 2) Participant: Inclusion criteria: age of 38 and 42 weeks; Five-minute Apgar score less than 3 at birth or delay in breathing for more than 5 minutes after birth; lethargy; seizures; abnormal neonatal reflexes; hypotonia in the early stages of birth Exclusion criteria: two twins; Congenital malformations; Chromosomal abnormalities; Congenital infection or Koryoamnyotit;); Encephalopathy 3) Intervention: Patients were divided into two groups of 15 people, in addition to routine therapy for patients with hypoxemic encephalopathy at birth, after the initial blood sample was taken from the patients were treated with 20 mg/kg intravenous phenobarbital within 6 hours of birth and second group not receive additional doses of phenobarbital 5) Comparison: Two weeks 6) Outcome: reduction of Nitric oxide level

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090919101N1**
Registration date: **2014-09-17, 1393/06/26**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-17, 1393/06/26

Registrant information

Name

Gholamreza Panahandeh

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

panahandeh@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of phenobarbital on the outcome of early ischemic encephalopathy Hypoxemic

Public title

The effect of phenobarbital on the outcome of early ischemic encephalopathy Hypoxemic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 38 and 42 weeks; Five-minute Apgar score less than 3 at birth or delay in breathing for more than 5 minutes after birth; lethargy; seizures; abnormal neonatal reflexes; hypotonia in the early stages of birth Exclusion criteria: two twins; Congenital malformations; Chromosomal abnormalities; Congenital infection or Koryoamnyotit;); Encephalopathy

Age

From **1 day** old to **1 day** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Shahrekord,Rahmatieh, Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

Approval date

2014-08-03, 1393/05/12

Ethics committee reference number

5-8-92

Health conditions studied

1

Description of health condition studied

Hypoxic ischaemic encephalopathy of newborn

ICD-10 code

P91.6

ICD-10 code description

Hypoxic ischaemic encephalopathy of newborn, unspecified

Primary outcomes

1

Description

reduction of Nitric oxide level

Timepoint

A week later

Method of measurement

sampling

Secondary outcomes

empty

Intervention groups

1

Description

The first group receive 20 mg/kg intravenous phenobarbital within 6 hours of birth

Category

Treatment - Drugs

2

Description

The second group not receive additional doses of phenobarbital

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hajar Hospital

Full name of responsible person

Panahandeh Gholamreza

Street address

Shahrekord University Of Medical Sciences

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University of Medical Scie

Full name of responsible person

Vice chancellor for research of Shahrekord University of Medical Scie

Street address

Shahrekord, Shahrekord University of Medical Sciences

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of Medical Scie

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Panahandeh Gholamreza

Position

Pediatric Endocrinologist, Assistant Professor

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty