

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of seizures in infants with moderate and severe asphyxia treated with intravenous acetaminophen

Protocol summary

Study aim

Evaluation of seizures in infants with moderate to severe asphyxia treated with intravenous acetaminophen

Design

The intervention group will include infants who will be given intravenous acetaminophen at a dose of 10 mg / kg for 3 days. control group consisting of moderate and severe asphyxia patients who were previously admitted to the ward.

Settings and conduct

This study was performed on 60 infants with moderate to severe asphyxia admitted to the neonatal intensive care unit of Imam Reza Hospital in Mashhad. Neonates were divided into two groups. The intervention group is given intravenous acetaminophen in addition to routine treatment for asphyxia. The same group of the mentioned treatments are performed routinely. Infants are monitored for seizures during hospitalization. Babies who have evidence of seizures will have an EEG (brain scan) and the brain scan will be checked by the Neuroscience Service and will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Term neonates with a gestational age greater than 37 weeks with a weight over 2 kg at birth and without asymptomatic structural abnormalities, umbilical cord pH below 7 and base deficit (open deficiency) more than 12 mmol / lit and Apgar score of 4 or Less in the first minute and 6 or less in the fifth minute Exclusion criteria: preterm infants, infants with structural abnormalities, infants under 2 kg, genetic disorders, neuromuscular disorders

Intervention groups

The intervention group will include infants who will be given intravenous acetaminophen at a dose of 10 mg / kg for 3 days. The control group patients who were previously admitted to the ward and received routine treatments in the ward.

Main outcome variables

The main outcome of the study in the intervention group

was the incidence of seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081021001378N14**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **retrospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

farhata@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of seizures in infants with moderate and severe asphyxia treated with intravenous acetaminophen

Public title
Evaluation of seizures in infants with moderate and severe asphyxia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
term newborn with 37 week gestational age more than 2 kg birth weight pH less than 7 base deficit more than 12 mmol/lit
Exclusion criteria:
preterm infants Anomalies less than 2 kg birth weight
Genetic disorders Neuromacular disorders

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 Mashhad University of Medical Sciences

Street address

Ghoreshi Bul, Daneshgah Ave, Mashhad, Iran

City

Mashahd

Province

Razavi Khorasan

Postal code

3791316

Approval date

2020-10-06, 1399/07/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.443

Health conditions studied

1

Description of health condition studied

moderate and severe asphyxia

ICD-10 code

P21

ICD-10 code description

Birth asphyxia

Primary outcomes

1

Description

The incidence of seizures

Timepoint

duration of hospitalization

Method of measurement

Based on clinical signs

2

Description

Time of start feeding

Timepoint

From the beginning of hospitalization to the end of hospitalization

Method of measurement

Based on abdominal examination, the presence of intestinal sounds and the absence of vomiting

3

Description

feeding tolerance

Timepoint

From the beginning of feeding to the end of hospitalization

Method of measurement

Abdominal examination, clinical observation of the infant and evaluation for vomiting or malnutrition

Secondary outcomes

1

Description

Evaluation of heart disorder at the end of acetaminophen treatment

Timepoint

duration of hospitalization

Method of measurement

Based on clinical signs and then if there are echocardiographic symptoms

Intervention groups

1

Description

Intervention group: They will include infants who will be given an intravenous acetaminophen at a dose of 10 mg / kg for 3 days. Routine daily treatments are also performed.

Category

Treatment - Drugs

2

Description

Control group: Patients with supportive and routine treatment in asphyxia: cardio respiratory monitoring, respiratory support if necessary, Restriction of neonatal fluid intake and injectable erythropoietin

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

neonatal intensive care unite of Imam Reza Hospital

Full name of responsible person

Mohadese Khakpour

Street address

Neonatal intensive Care Unite, Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran

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9137913316

Phone

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Email

khakpourmh981@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayoir Mobarhan

Street address

Ghoreshi Bul, Daneshgah St, Mashhad, Iran

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mhadese Khakpour

Position

neonatologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohadese Khakpour

Position

noenatologist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

محدثه خاکپور

Position

neonatologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

All data can be shared after patients are made unidentified

When the data will become available and for how long

data can be accessible 6 months after results are published

To whom data/document is available

Data can be accessible through an email to the corresponding author

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institutions

From where data/document is obtainable

After sending a request email to the corresponding author data will be sent in 2 month

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

Carrying out analysis on data is permitted

Comments