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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3852 1121
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 Ghayoiur Mobarhan
Street address
Ghoreshi Bul, Daneshgah St, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
37913316
Phone
+98 51 3852 1121
Email
khakpourmh981@mums.ac.ir
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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
38521121
Email
khakpormh981@mums.ac.ir

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

Pediatrics

Street address

Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

385521121

Email

khakpourmh981@mums.ac.ir

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

Street address

Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

38521121

Email

khakpourmh981@mums.ac.ir

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