Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of azithromycin and topiramate on prooxidant antioxidant balance, interleukin 6, 8 and 1 in infants with hypoxic-ischemic encephalopathy

Protocol summary

Study aim

Determining the effect of azithromycin or topiramate on IL-6, IL-8 and PAB in infants with hypoxic ischemic encephalopathy

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 124 patients

Settings and conduct

This clinical trial will be conducted on infants with hypoxic ischemic encephalopathy hospitalized in the hospitals of Mashhad University of Medical Sciences. After obtaining informed consent from the mothers and completing the informed consent form, infants with a gestational age of more than 32 weeks are included in the study.

Participants/Inclusion and exclusion criteria

Criteria for individuals' entry into the study: Infants with a gestational age of 32 weeks or more and a definitive diagnosis of hypoxic-ischemic encephalopathy, which includes at least two of the following: History of identifiable birth events (placenta separation, uterine rupture, umbilical cord prolapse) along with birth monitoring disorders, birth trauma, or difficult birth. Umbilical cord pH less than 7 or blood pH less than 7.2 in the blood sample within the first hour of birth. BE > -12 in the blood sample within the first hour of birth or umbilical cord. Non-entry criteria: congenital malformation, maternal chorioamnionitis

Intervention groups

Infants who entering the study are,, in the four arms of the study as follows: Control group: infants who receive conventional treatment and are under care. Group receiving allopurinol: in addition to conventional measures, 40 mg/kg allopurinol tablets (with a time interval of 12 hours) on the first day. Erythropoietin receiving group: In this group, erythropoietin is prescribed at a dose of 1000 IU/kg on the first, second and third day. The group receiving erythropoietin and allopurinol together

Main outcome variables

Changes in the PAB, interleukin 6 and 8 before and after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N10**
Registration date: **2023-09-19, 1402/06/28**
Registration timing: **prospective**

Last update: **2023-09-19, 1402/06/28**
Update count: **0**

Registration date

2023-09-19, 1402/06/28

Registrant information

Name
Hassan Boskabadi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2028-02-20, 1406/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of azithromycin and topiramate on prooxidant antioxidant balance, interleukin 6, 8 and 1 in infants with hypoxic-ischemic encephalopathy

Public title

Comparison of the effects of topiramate and azithromycin on the balance of antioxidants, interleukin 6, 8 and 1 in infants with cerebral complications of birth asphyxia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of identifiable birth events (placenta separation, uterine rupture, umbilical cord prolapse) along with birth monitoring disorders Umbilical cord pH less than 7 or less than 7.2 in the blood sample in the first hour of birth BE<-12 in umbilical cord blood sample in the first hour of birth The need for positive pressure ventilation for more than one minute in the delivery room

Exclusion criteria:

Congenital malformations maternal chorioamnionitis Intrauterine growth retardation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

The block method will be used as a reliable randomization method that leads to balanced allocation of people in treatment groups at the end of each block. https://www.sealedenvelope.com/simple-randomiser/v1/lists is used to prepare random blocks with variable sizes. The output of the site is such that, depending on the number of samples and the proposed sizes of the blocks, a certain number of blocks with different sizes (4 and 8) and with different sequences of block content is provided, which is followed by the content of each block in a sealed envelope and then one of the blocks is randomly selected and depending on the order of the sequence, the person in question is placed in one of the arms of the study. In the same way, after the completion of the first block, the second block is randomly selected and this continues until the last block and assigning the last person to the study arms. As a rule, by assigning the last sheet of the last block, the patients are grouped equally in the two arms of the study and the balance between the groups is established.

Blinding (investigator's opinion)

Double blinded

Blinding description

The first layer of blinding occurs in the group of participants in such a way that after obtaining informed consent from the parents, no information regarding the therapeutic process of the infant will be provided to them. Given that the infants are kept in the NICU and away from their parents, medication will be administered at times when the parents are not present. The second layer pertains to the outcome evaluator, who will only have access to the names of the participants and will have no information regarding the patient's medication card. Finally, the collected data from both study groups A and B will be delivered to the analyst, who will have no information regarding the allocation of titles A and B to the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.MUMS.MEDICAL.REC.1402.276

Street address

ahmadabad St

City

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Province

Razavi Khorasan

Postal code

9176699199

Approval date

2023-10-24, 1402/08/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.276

Health conditions studied

1

Description of health condition studied

Hypoxic Ischemic encephalopathy

ICD-10 code

P91.60

ICD-10 code description
Hypoxic ischemic encephalopathy [HIE], unspecified

Primary outcomes

1

Description
pro oxidant antioxidant balance
Timepoint
The beginning of the study
Method of measurement
Pro-Oxidant Antioxidant Balance (PAB) assay

2

Description
interleukin 6
Timepoint
The beginning of the study
Method of measurement
Enzyme-linked immunosorbent assay

3

Description
interleukin 8
Timepoint
The beginning of the study
Method of measurement
Enzyme-linked immunosorbent assay

4

Description
interleukin 1 B
Timepoint
The beginning of the study
Method of measurement
Enzyme-linked immunosorbent assay

Secondary outcomes

1

Description
Pro-Oxidant Antioxidant Balance
Timepoint
Three days after birth
Method of measurement
Pro-Oxidant Antioxidant Balance assay

2

Description
Interleukin 6
Timepoint
Three days after birth
Method of measurement
Enzyme-linked immunosorbent assay

3

Description
Interleukin 8
Timepoint
Three days after birth
Method of measurement
Enzyme-linked immunosorbent assay

4

Description
Interleukin 1B
Timepoint
Three days after birth
Method of measurement
Enzyme-linked immunosorbent assay

Intervention groups

1

Description
Intervention group: infants suffered from hypoxic ischemic encephalopathy who receive azithromycin (20 mg/kg/day, orally for 3 days and then 10 mg/kg/day, orally for 2) and/or Topiramate(10 mg/kg/day, orally for 3 days)
Category
Treatment - Drugs

2

Description
Control group: infants who receive conventional treatments (respiratory support, fluid management, anticonvulsant drugs, reduction of intracranial pressure, maintenance of blood pressure and correction of hypoglycemia, acidosis and electrolyte disorders)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Hassan Boskabadi
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number
۴۰۱۱۸۸۰

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
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
available for people working in academic institutions
Under which criteria data/document could be used
upon reasonable request from corresponding author
From where data/document is obtainable
Boskabadih@mums.ac.ir
What processes are involved for a request to access data/document
If there is a need for the data for another research project, access to the data is possible, provided that the intellectual rights of the authors, the financial provider, and the rights of the project are respected.
Comments