Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of melatonin in pro-oxidant antioxidant balance of neonates with hypoxic ischemic encephalopathy: A Randomized Parallel Clinical Trial

Protocol summary

Study aim

determine the effect of melatonin in pro-oxidant antioxidant balance of neonates with hypoxic ischemic encephalopathy

Design

Two arm (intervention and control) Superiority, parallel group randomized (block) with Allocation Concealment trial with blinded care and outcome assessment on 70 infant

Settings and conduct

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

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: Identifiable intrapartum events (placental abruption, uterine rupture, umbilical cord prolapse) accompanied by intrapartum monitoring disorders, intrapartum fever, 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. Criteria for exiting the study: Congenital malformations Congenital infections Chorioamnionitis Encephalopathy due to genetic disease Encephalopathy due to metabolic diseases Hyperbilirubinemia encephalopathy

Intervention groups

In both the intervention and control groups, infants receive MgSO4 at a rate of 250 mg/kg/day with a one-hour infusion and blood pressure control in the first hour, the second day, and the third day. In the intervention group, infants receive 10 mg/kg/daily of oral melatonin for 5 days.

Main outcome variables

Level of consciousness, duration of feeding (days), hospitalization (days), need for oxygen (days), number of seizures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230605058385N1**
Registration date: **2023-09-02, 1402/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-02, 1402/06/11**
Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

TIna Loghmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2202

Email address

loghmanit4011@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-02-29, 1402/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of melatonin in pro-oxidant antioxidant balance of neonates with hypoxic ischemic encephalopathy: A Randomized Parallel Clinical Trial

Public title

melatonin in neonates with hypoxic encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

neonates with pregnancy age more than 32 weeks diagnosis hypoxic ischemic encephalopathy parent consent

Exclusion criteria:

congenital malformations congenital infections maternal chorioamnionitis heretical encephalopathy metabolic encephalopathy hyperbilirobinemic encephalopathy

Age

To **10 days** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In the upcoming clinical trial, we will utilize block randomization to ensure a balanced allocation between the intervention and control groups. A computer algorithm from the website sealedenvelope.com will generate blocks of a predetermined size (e.g., 4 or 6). Within each block, an equal number of participants will be allocated to both the intervention and control groups. Sealed, numbered envelopes will be used for this purpose. Instead of containing a drug or placebo, each envelope will simply have a label indicating the group—either "Control" or "Intervention"—to which the participant is to be allocated. These envelopes will be distributed to participants based on the block randomization algorithm generated by sealedenvelope.com. An independent team separate from the principal investigators will manage this process to ensure that the randomization is executed accurately and without bias.

Blinding (investigator's opinion)

Triple 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

Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences

Street address

ferdowsi campus

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2023-05-07, 1402/02/17

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.263

Health conditions studied

1

Description of health condition studied

Hypoxic ischemic encephalopathy [HIE]

ICD-10 code

P91.6

ICD-10 code description

Hypoxic ischemic encephalopathy [HIE]

Primary outcomes

1

Description

Pro-Oxidant Antioxidant Balance

Timepoint

three days after birth

Method of measurement

Pro-Oxidant Antioxidant Balance (PAB) assay

Secondary outcomes

1

Description

Pro-Oxidant Antioxidant Balance

Timepoint

seven days after birth

Method of measurement

Pro-Oxidant Antioxidant Balance (PAB) assay

Intervention groups

1

Description

Intervention group: infants suffered from hypoxic ischemic encephalopathy who receive Melatonin (10 mg/kg/day, orally for 5 days)

Category

Treatment - Drugs

2

Description

Control group: infants suffered from hypoxic ischemic encephalopathy who do not receive Melatonin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Hasan Boskabadi

Street address

Ahmad Abad

City

Mashhad

Province

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Postal code

9176699199

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b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

MOhsen Mohebati

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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

حسن بسکابادی

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Tina Loghmani

Position
student

Latest degree
Medical doctor

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
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