Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The evaluation of Melatonin effect on short outcome in newborns with hypoxic ischemic encephalopathy

Protocol summary

Study aim
The evaluation of Melatonin effect on short outcome in newborns with hypoxic ischemic encephalopathy
Design
This is a clinical trial, phase II, in which 66 eligible patients will be assigned to the intervention and control groups
Settings and conduct
The eligible newborns with hypoxic- ischemic-encephalopathy referring to the Fatemieh Hospital in Hamadan city during the study period will be enrolled .
Participants/Inclusion and exclusion criteria
Inclusion criteria: At least one of the diagnostic criteria of HIE include: APGAR score <5 at 5 minutes, Fetal heart rate <60 bpm, Prolonged metabolic acidosis(>1 hour), Need of positive pressure ventilation>1 min or delay in crying >10 min of birth, Occurrence of acute perinatal events, Seizures occur in the first 24 to 48 hours after birth. Exclusion criteria: Gestational age <36weeks, Congenital anomalies, Unperforated anus, Intracranial hemorrhage
Intervention groups
Intervention group: Routine treatment plus intravenous injection of melatonin 1O mg/kg day on the first, second and third days and then every other day on the fifth, seventh, and ninth days to a maximum of 6 doses, Control group: Just routine treatment
Main outcome variables
Primary outcome: Seizure attacks, time of onset of consciousness, the occurrence of death, duration of hospitalization, time to start oral nutrition Secondary outcome: Drug complications such as thrombocytopenia.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160523028008N19**
Registration date: **2021-12-06, 1400/09/15**
Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**
Update count: **0**
Registration date
2021-12-06, 1400/09/15

Registrant information
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Name of organization / entity
Hamadan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-21, 1400/09/30
Expected recruitment end date
2022-03-21, 1401/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of Melatonin effect on short outcome in newborns with hypoxic ischemic encephalopathy

Public title
evaluation of Melatonin effect on short outcome in

newborns with hypoxic ischemic encephalopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least one of diagnostic criteria of HIE include: 1-APGAR score <5 at 5 minutes Fetal heart rate <60 bpm Prolonged metabolic acidosis(>1 hour) Need of positive pressure ventilation>1 min or delay in crying >10 min of birth Occurrence of acute perinatal events Exclusion criteria Seizures occur in the first 24 to 48 hours after birth

Exclusion criteria:

Gestational age <36weeks Congenital anomalies Unperforated anus Intracranial hemorrhage

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The person analyzing the results is not aware of patient allocation, so the study is single-blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Postal code

6517838695

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.UMSHA.REC.1400.452

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

Seizure attacks

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

2

Description

Time of onset of consciousness

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

3

Description

Occurrence of death

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

4

Description

Duration of hospitalization

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

Based on the medical document

5

Description

Drug complications such as induced topical hypothermia, bradycardia and subcutaneous necrosis

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

With clinical examination

6

Description

Time to start oral nutrition

Timepoint

From the beginning of the intervention until two weeks thereafter

Method of measurement

By taking a history

Secondary outcomes

1

Description

Drug complications such as thrombocytopenia

Timepoint

From the beginning of the intervention up to two weeks late

Method of measurement

By laboratory tests

Intervention groups

1

Description

Intervention group: Routine treatment plus intravenous injection of melatonin 1O mg/kgday on the first, second and third days and then every other day on the fifth, seventh, and ninth days to a maximum of 6 doses

Category

Treatment - Drugs

2

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyeh Hospital

Full name of responsible person

Behnaz Basiri

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Fatemiyeh Hospital, Kermanshah street, Hamedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Kiani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work
Pediatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is not a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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