

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Fatemeh 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 10 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

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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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Province

Hamadan

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 10 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

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

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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