

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of oral melatonin in the treatment of acute respiratory distress syndrome in neonates

Protocol summary

Study aim

Investigating the effect of oral melatonin in the treatment of acute respiratory distress syndrome in infants

Design

The current study is a randomized, block-blocked, double-blind clinical trial that includes two control and intervention groups, in which 37 babies will be studied in each group, and finally, the data will be analyzed with spss 16 software. The phase of this study is 3, that is, it compares the results of treatment of people using new treatment and the results of treatment of people using standard treatment. The groups in this study are parallel and two groups are studied during a specific time.

Settings and conduct

Seventy four premature babies weighing less than 2500 grams or gestational age less than 37 weeks born in Imam Reza Hospital Mashhad were randomly divided into two groups, one group was given oral melatonin and standard treatment (surfactant therapy with respiratory support). and in the other group, only standard treatment will be done. The dose of melatonin is 10 mg/kg for three days, which is prescribed once a day.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: infants with RDS beyond the respiratory distress. Exclusion criteria include: neonatal sepsis (positive blood culture); respiratory diseases other than RDS (chest x-ray examination); cardiovascular diseases (pulse oximetry examination of the right hand and lower limbs) or diseases of the central nervous system; kidney failure.

Intervention groups

The intervention group will include infants who, in addition to the standard treatment, will be treated with oral melatonin at a dose of 10 mg/kg per day for three days. The control group will receive standard treatment (surfactant therapy and respiratory support).

Main outcome variables

The oxidant test, C-reactive protein test (CRP

)respiratory distress score of the newborn; the number of surfactant doses are investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130308012743N3**

Registration date: **2022-11-13, 1401/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-13, 1401/08/22**

Update count: **0**

Registration date

2022-11-13, 1401/08/22

Registrant information

Name

Ezat Khodashenas

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1727 3943

Email address

khodashenase@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of oral melatonin in the treatment of acute respiratory distress syndrome in neonates

Public title
oral melatonin in the treatment of acute respiratory distress syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infants with respiratory distress syndrome with any grade of respiratory distress
Exclusion criteria:
Neonatal sepsis Neonates with Respiratory distress disease other than RSD Neonates with cardiovascular diseases or diseases of the central nervous system
Neonates with kidney failure

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of infants will be done using block methods. A random sequence will be generated using four blocks of sealed envelope.com. The envelopes will be printed by the researcher after randomization and will be placed inside the envelopes and the envelope lids will be closed. Envelopes are numbered in random order. Then, we first explain the purpose of the study to the person and he / she will sign the informed consent and receive the intervention based on the envelope number and the order specified in it.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, two groups of people under study, who are infants, and the outcome evaluator were blinded to the way the study was conducted.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Connate of Mashhad University of Medical Sciences

Street address

Qureshi Bul, Daneshgah Ave, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2022-05-17, 1401/02/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.154

Health conditions studied

1

Description of health condition studied

Distress syndrome of neonates

ICD-10 code

P22.0

ICD-10 code description

P22.0Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Pro-antioxidant

Timepoint

Laboratory examination is done on the first and third day of birth.

Method of measurement

By measuring pro-antioxidant test

2

Description

C-reactive protein factor (CRP)

Timepoint

Laboratory examination is done on the first and third day of birth.

Method of measurement

By measuring CRP

3

Description

respiratory distress score

Timepoint

Laboratory examination is done on the first and third day of birth.

Method of measurement

By Measuring Respiratory distress score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will include infants who, in addition to the standard treatment, will be treated with oral melatonin at a dose of 10 mg/kg per day for three days.

Category

Treatment - Drugs

2

Description

Control group: They will undergo standard treatment (surfactant therapy and respiratory support).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Farnaz Mousavi

Street address

Ibn Sina Ave, Imam Reza Hospital , Mashhad , Iran

City

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9137916616

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Email

dr.farnazmousavi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

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Qoreshi Bul, Daneshgah Ave, Mashhad, Iran

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ghayourm@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

Farnaz Mousavi

Position

Fellowship of neonatology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farnaz mousavi

Position

fellowship of neonatology

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Person responsible for updating data

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Position

neonatology

Latest degree

Specialist

Other areas of specialty/work

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Fax

Email

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 institution

From where data/document is obtainable

After sending a request email to the corresponding author data will be sent in 1 month

What processes are involved for a request to access data/document

Carrying out analysis on data is permitted

Comments