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 recieve 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 Scienses

Country

Iran (Islamic Republic of)

Phone

+98 51 1727 3943

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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 sealedenvelope.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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad 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
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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Position
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Latest degree
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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
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