Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of melatonin in the prevention of bronchopulmonary dysplasia in neonates admitted to Neonatal intensive care unit

Protocol summary

Study aim
Determining the effect of melatonin in the prevention of bronchopulmonary dysplasia in infants admitted to the Neonatal intensive care unit Mahdieh Hospital

Design
This study is a randomized clinical trial. Allocation of samples to intervention and control groups is done by randomization of random blocks.

Settings and conduct
In this study, infants hospitalized in the neonatal intensive care unit are included in the study. In the intervention group, in addition to the surfactant, melatonin drops at a dose of one tenth of a milligram per kilogram of the baby's weight are administered as oral drops for three days, and in the control group, in addition to the intratracheal surfactant, a placebo drop similar to the use of melatonin is prescribed. The outcome variable is measured before the start of the study, 28 and 56 days after birth.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Premature neonates between 26 and 32 weeks with respiratory distress syndrome need surfactant injection exclusion criteria: Apgar five minutes less than four Evidence of necrotizing enterocolitis before surfactant administration chromosomal disorders, esophageal atresia, diaphragmatic hernia Evidence of congenital heart diseases other than Atrial Septal Defect and Patent ductus arteriosus Major congenital anomaly of heart failure requiring treatment

Intervention groups
intervention group: In addition to surfactant, melatonin drops at a dose of 0.1 milligram per kilogram of the baby's weight will be administered as oral drops for three days. Control group: In addition to intratracheal surfactant, placebo drops similar to melatonin are prescribed.Placebo drops prepared by a pharmacologist and containing normal saline are prescribed.

Main outcome variables
BRONCHOPULMONARY DYSPLASIA

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230526058294N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date
2023-08-19, 1402/05/28

Registrant information

Name
Fatemeh Serati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 7021

Email address
f.serati128@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-20, 1402/01/31

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of melatonin in the prevention of bronchopulmonary dysplasia in neonates admitted to Neonatal intensive care unit

Public title

The effect of melatonin in the prevention of bronchopulmonary dysplasia in neonates admitted to Neonatal intensive care unit of Mahdieh Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premature neonates between 26 and 32 weeks with respiratory distress syndrome need surfactant injection

Exclusion criteria:

Apgar five minutes less than four Evidence of necrotizing enterocolitis before surfactant administration chromosomal disorders, esophageal atresia, diaphragmatic hernia Evidence of congenital heart diseases other than Atrial Septal Defect and Patent ductus arteriosus Major congenital anomaly of heart failure requiring treatment

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients in two groups was done by random block allocation method.The allocation sequence was generated using the free web system https//:www.sealedenvelope.com.To produce the sequence, the number of subjects in each block is 4, and the letters A are for the intervention group and the letters B are for the control group.Finally, 60 samples (15 blocks) have been produced in two groups A and B.Then, the cards containing the blocks are placed inside the standard envelope and in this way the concealment allocation is observed. Based on the selection of eligible neonates, an envelope is randomly picked by the researcher and the method of allocation is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

The doctor evaluating the outcome does not know how to assign drugs to patients. After collecting all the samples, the data analyst will analyze the intervention and control groups based on the code made by the pharmacologist.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق در پژوهش‌های زیست پزشکی دانشگاه علوم پزشکی شهیدی بهشتی

Street address

Shariati St. Mofid Children's Hospital

City

tehran

Province

Tehran

Postal code

8313774691

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.SBMU.MSP.REC.1401.640

Health conditions studied

1

Description of health condition studied

bronchopulmonary dysplasia

ICD-10 code

P27.1

ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description

BRONCHOPULMONARY DYSPLASIA

Timepoint

Before initiation of the study, 28 and 56 days after birth

Method of measurement

Inspiratory oxygen fraction:The percentage of oxygen that is present in the air of the newborn, in order to investigate respiratory distress syndrome, the need for oxygen or respiratory assistance for more than 28 days after birth to investigate bronchopulmonary dysplasia

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to surfactant, melatonin drops at a dose of 0.1 milligram per kilogram of the baby's weight will be administered as oral drops for three days.
Category
Treatment - Drugs

2

Description
Control group: In the control group, in addition to intratracheal surfactant, placebo drops similar to melatonin are prescribed.Placebo drops prepared by a pharmacologist and containing normal saline are prescribed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh Hospital
Full name of responsible person
fatemeh serati
Street address
Fadaeiyan Eslam
City
tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
f.serati128@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
معاونت تحقیقات و فناوری دانشگاه علوم پزشکی شهید بهشتی
Street address
Arabi st, Velenjak st
City
tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9781
Email
f.serati128@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
fatemeh serati
Position
دکترای تخصصی بالینی
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Fadaeiyan Eslam
City
tehran
Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
Email
f.serati128@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
fatemeh serati
Position
Clinical Specialist
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address

Fadaeiyan Eslam.Mahdiyeh Hospital

City
tehran

Province
Tehran

Postal code
1185817311

Phone
+98 21 5506 2628

Email
f.serati128@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
fatemeh serati

Position
Clinical Specialist

Latest degree
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Pediatrics

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Fadaeiyan Eslam. Mahdiyeh Hospital

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Email
f.serati128@gmail.com

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
Undecided - It is not yet known if there will be 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
Data can be shared potentially after patients became unrecognizable.

When the data will become available and for how long
After completing the results and analyzing the data, access to them is allowed.

To whom data/document is available
Researchers working in academic institutions or research centers

Under which criteria data/document could be used
Researchers are licensed by the research committee

From where data/document is obtainable
After publishing the article, visit the magazine site to get more information write to f.serati128@gmail.com

What processes are involved for a request to access data/document
Researchers can can receive the necessary response after two weeks by sending an e-mail to the person in charge.

Comments