

# 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 Mahdiah 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 pharmacist 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**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Fadaeiyan Eslam. Mahdiyeh Hospital

**City**

tehran

**Province**

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**Postal code**

1185817311

**Phone**

+98 21 5506 2628

**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 receive the necessary response after two weeks by sending an e-mail to the person in charge.

### Comments