

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Melatonin Efficacy in Treatment of Respiratory Distress Syndrome and Prevention of Bronchopulmonary Dysplasia

#### Protocol summary

##### Study aim

The effect of melatonin on treatment of respiratory distress syndrome and prevention of bronchopulmonary dysplasia

##### Design

Eighty preterm infants weighing less than 1250 g or gestational age 26 to 32 born in Al-Zahra Hospital were randomly divided into two groups. Informed consent will be given in addition to surfactant at the rate of 5 mg / kg / day for up to three days of melatonin with the surfactant. The clinical trial is a double-blind study.

##### Settings and conduct

80 neonates, endotracheal surfactant control group, other group endotracheal surfactant and melatonin tablets 5 mg / kg via oral-gastrointestinal tract at Alzahra hospital in Tabriz. Visiting physicians and nurses caring for neonates are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 80 preterm infants weighing less than 1250 g or gestational age 26 to 32 born at Alzahra Hospital and hospitalized with neonatal respiratory distress syndrome requiring surfactant Will be studied. Exclusion criteria: Apgar score less than four minutes, evidence of congenital heart disease other than ASD and PDA, evidence of necrotizing enterocolitis prior to surfactant administration, presence of major congenital anomaly, treatment failure, shock, clear chromosomal abnormalities, atrial fibrosis, atresia .

##### Intervention groups

Newborns are randomly divided into two groups. One group is given intratracheal surfactant and the other group after receiving informed consent in addition to surfactant 5 mg / kg / day up to three days melatonin. It will be prescribed with surfactant.

##### Main outcome variables

Breathing oxygen fraction: Percentage of oxygen present in infant's nasal air to assess respiratory distress syndrome Need oxygen or respiratory support for more than 28 days of birth to evaluate bronchopulmonary

dysplasia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190518043629N1**

Registration date: **2020-04-07, 1399/01/19**

Registration timing: **retrospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **0**

##### Registration date

2020-04-07, 1399/01/19

##### Registrant information

##### Name

majid fekri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3236 6111

##### Email address

majid.fekri1362@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-24, 1398/06/02

##### Expected recruitment end date

2019-11-22, 1398/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of Melatonin Efficacy in Treatment of Respiratory Distress Syndrome and Prevention of Bronchopulmonary Dysplasia

### Public title

Evaluation of Melatonin Efficacy in Treatment of Respiratory Distress Syndrome and Prevention of Bronchopulmonary Dysplasia

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Premature Neonates between 26 and 32 weeks of age born at Al-Zahra Hospital Respiratory distress syndrome requires injection of surfactant

#### Exclusion criteria:

Less than four minutes Apgar , fewer than four Evidence of congenital heart disease other than ASD and PDA Evidence of necrotizing antraloctosis before the administration of surfactant Congenital major anomalies, heart failure requiring treatment Shock Clear chromosomal abnormalities Esophageal atresia Diaphragmatic hernia

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The infants were randomly assigned to two groups. A random number list of 1 to 80 will be created using Random number generator and the infants will be randomly assigned to two intervention groups . The 1: 1 block randomization method will be used to achieve two groups with equal sample size.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study,the physician visiting neonates is not aware receiving melatonin by neonates, the nurse who records the patients data and who perform data analysis are blind about study purposes.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee for Research in Tabriz University of Medical Sciences

##### Street address

ARTESH Ave

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138665793

#### Approval date

2019-08-19, 1398/05/28

#### Ethics committee reference number

IR.TBZMED.REC.1398.574

## Health conditions studied

### 1

#### Description of health condition studied

respiratory distres syndrom

#### ICD-10 code

P22.9

#### ICD-10 code description

Respiratory distress of newborn, unspecified

### 2

#### Description of health condition studied

Bronchopolmonary displasia

#### ICD-10 code

P27.1

#### ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

## Primary outcomes

### 1

#### Description

Bronchopulmonary dysplasia

#### Timepoint

Requires more than 21% oxygen for at least 28 days

#### Method of measurement

Fractional oxygen (Fio2) read by blender or ventilator and recorded in the file

## Secondary outcomes

## 1

### **Description**

Respiratory distress syndrome: Symptoms of respiratory distress due to surfactant deficiency mainly caused in preterm infants.

### **Timepoint**

One hour and four hours after treatment and the number of times the surfactant is needed

### **Method of measurement**

Existence of respiratory distress requiring intubation or establishment of NCPAP with at least 5 cm water pressure at first hour of birth with Fractional oxygen (Fio2) requires respiratory fraction greater than 40% at 26 weeks gestation and respiratory fraction greater than 30% at 26 weeks gestation. Or continued respiratory distress, despite the onset of NCPAP, which is diagnosed by a neonatal or pediatric specialist or pediatric resident.

## **Intervention groups**

### 1

#### **Description**

Control group: In this group, the surfactant is injected into the trachea. How to inject Surfactant by Insure, the patient will be intubated and post-injection will be extubated and subjected to N-CPAP but will remain intubated if the respiratory distress and SPO2 are not corrected.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: In this group, after obtaining informed consent in addition to the surfactant, 5 mg / kg daily up to three days of melatonin will be administered via NGtube with the surfactant.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Al-Zahra Hospital in Tabriz

##### **Full name of responsible person**

Majid Fekri

##### **Street address**

Artesh Ave

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

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##### **Phone**

+98 41 3553 8947

#### **Email**

majid.fekri1362@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Samiei

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Artesh Ave

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##### **Email**

Samiei.moh@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Majid Fekri

##### **Position**

neonatal assistant

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Information about the main outcome of this study is shared after unidentifiable individuals.

### When the data will become available and for how long

After printing and analyzing the results and data available since 2021.

### To whom data/document is available

The data of this study are applicable to academic and scientific researchers and medical and paramedical students.

### Under which criteria data/document could be used

The data in this study are solely for the use of academic and scientific researchers and medical and paramedical students.

### From where data/document is obtainable

Applicants can contact the following people by email: 1. Majid Fekri : majid.fekri1362@gmail.com 2 . Gharehbaghi : gharehbaghimm@yahoo.com

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

The applicant can contact the Alzahra hospital in Tabriz in person or the e-mail address listed above.

### Comments