

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

5138665793

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

Street address

Artesh Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3556 6449

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

Street address

Artesh Ave

City

tabriz

Province

East Azarbaijan

Postal code
5138665793
Phone
+98 41 3556 9543
Email
majid.fekri1362@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Manijeh Mostafa Gharabaghi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Artesh Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3556 9543
Email
gharehbaghimm@yahoo.com

Person responsible for updating data

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
Street address
Artesh Ave

City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3556 9543
Email
Majid.fekri1362@gmail.com

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