Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the consequences of using two methods of "continuous positive airway pressure" and "high frequency oscillation" in the treatment of respiratory distress in premature neonates

Protocol summary

Study aim

Determining the consequences of using two methods of "continuous positive airway pressure" and "high frequency oscillation" in the treatment of respiratory distress in premature neonates

Design

Clinical trial without control group will start with two parallel groups without blinding and randomized on 78 patients. The allocation of samples in each group will do by blocked randomization

Settings and conduct

Infants are randomly treated with either "continuous positive airway pressure" or "high frequency oscillation" for a maximum of 2-3 days. After the disease has healed, other methods such as oxygen therapy with an oxyhood or a mask are used. In both methods, nasal single pronge (3-4 cm inside the nose) is used. During both procedures, if the baby needs surfactant based on clinical signs and chest radiograph, the insure method will be performed and after extubation, the baby will be put back on the previous settings.

Participants/Inclusion and exclusion criteria

All premature infants (gestational age 28-24 weeks) Birth weight less than 2000 grams Hospitalization in neonatal intensive care unit due to respiratory distress

Intervention groups

Infants randomly treated with either "high frequency oscillation" or "continuous positive airway pressure" for a maximum of 2-3 days. After the disease has healed, other methods such as oxygen therapy with an oxyhood or a mask are used. In both methods, nasal single pronge (3-4 cm inside the nose) is used. During both procedures, if the baby needs surfactant based on clinical signs and chest X-Ray, the insure method will be performed and after extubation, the baby will be put back on the previous settings, In addition, the control group is not considered.

Main outcome variables

- Initial outcome: The baby needs to be intubated Success or failure of any method - Secondary consequence: Pulmonary or extrapulmonary complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190416043290N2**
Registration date: **2020-12-17, 1399/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-17, 1399/09/27**
Update count: **0**

Registration date

2020-12-17, 1399/09/27

Registrant information

Name

Raheleh Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 1316

Email address

raheleh.moradi1987@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the consequences of using two methods of "continuous positive airway pressure" and "high frequency oscillation" in the treatment of respiratory distress in premature neonates

Public title
Comparison of two methods of respiratory support in neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All premature neonates (gestational age of 28-34 weeks) Neonates with birth weight less than 2000 gr. Hospitalization in the neonatal intensive care unit due to respiratory distress during the first 24 hours after birth
Exclusion criteria:
Severe asphyxia (apgar of minutes 5 less than or equal to 6) Positive blood culture upon arrival at the neonatal intensive care unit Congenital malformations (whether pulmonary or extrapulmonary)
Age
To **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples are divided into 2 groups by Blocked Randomization method; Thus, the blocks will be 4 and, considering that the sample size is generally 78 people, 20 blocks of 4 will be considered.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics Committee of Tehran University of Medical Sciences
Street address
Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2020-09-30, 1399/07/09
Ethics committee reference number
IR.TUMS.IKHC.REC.1399.239

Health conditions studied

1

Description of health condition studied
respiratory distress of neonates
ICD-10 code
P22
ICD-10 code description
Respiratory distress of newborn

Primary outcomes

1

Description
Success or failure of any method
Timepoint
Maximum 3 days
Method of measurement
Need for endotracheal intubation or pulmonary or extrapulmonary complications

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Infants with a gestational age of 28-34 weeks, weighing less than 2000 grams and hospitalized in the neonatal intensive care unit with a diagnosis of respiratory distress during the first 24 hours of birth, entered the study and accidentally treated with the method of respiratory support as "continuous positive airway pressure " for a maximum of 2-3 days. In this method, a single pronge is used 3-4 centimeters inside the nose. During the treatment, if the baby needs

surfactant, based on clinical signs and chest radiography, the method of insure will be operated, and after extubation, the baby will be back to the previous settings. the brand of device used will be "Cindy" or "Ventilator" the amount of oxygen that reaches the patient in each inspiratory is regulated by 40-70% and the positive end expiratory pressure will be 4-6 centimeters of water. Intervention failure in this method is defined as continuous oxygen saturation below 90%, persistence of clinical symptoms or respiratory score above 5. After the disease has healed, other methods such as oxygen therapy with an oxyhood or a mask are used.

Category

Treatment - Devices

2

Description

Intervention group 2: Infants with a gestational age of 28-34 weeks, weighing less than 2000 grams and hospitalized in the neonatal intensive care unit with a diagnosis of respiratory distress during the first 24 hours of birth, entered the study and accidentally treated with the method of respiratory support as "high frequency oscillation " for a maximum of 2-3 days. In this method, a single pronge is used 3-4 centimeters inside the nose. During the treatment, if the baby needs surfactant, based on clinical signs and chest radiography, the method of insure will be operated, and after extubation, the baby will be back to the previous settings. the brand of device used will be "Stephanie Soufie"; the open airway pressure will be set at 10 centimeters of water and the frequency of the device will be 6-8 hertz. Intervention failure in this method is defined as continuous oxygen saturation below 90%, persistence of clinical symptoms or respiratory score above 5. After the disease has healed, other methods such as oxygen therapy with an oxyhood or a mask are used.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Dr. tahereh Esmaeilnia Shirvani

Street address

Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 2357

Fax

+98 21 6659 1315

Email

tesmaeilnia@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali sahraian

Street address

Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۵۳۷۶۱

Phone

+98 21 8163 3685

Fax

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raheleh Moradi

Position

Midwife-Researcher

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address
Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6119 2357

Fax
+98 21 6659 1315

Email
raheleh.moradi1987@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Tahereh Esmaeilnia

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Others

Street address
Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
0098 61192357

Email
tesmaeilnia@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Raheleh Moradi

Position
Midwife-Researcher

Latest degree
Master

Other areas of specialty/work
Reproductive Health

Street address
Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6659 1316

Fax
+98 21 6659 1315

Email
raheleh.moradi1987@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
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
Information on study outcomes can be shared.

When the data will become available and for how long
6 months after publication of results.

To whom data/document is available
Free and academic researchers

Under which criteria data/document could be used
Only information about the outcomes of the study is provided, which is unimpeded if the material and intellectual rights of the Maternal and Fetal Research Center are protected.

From where data/document is obtainable
Maternal, fetal & Neonatal Research Center, Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Boulevard, Tehran, Iran

What processes are involved for a request to access data/document
Visit in research center or communication by email: mfnhrc@tums.ac.ir

Comments