Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

A comparison of the effect of Nasal Continuous Positive Airway Pressure (NCPAP) vs Nasal high-frequency oscillation(NHFO) in the treatment of respiratory distress in preterm infants

Protocol summary

Study aim

A comparison of the effect of Nasal Continuous Positive Airway Pressure (NCPAP) vs Nasal high-frequency oscillation(NHFO) in the treatment of respiratory distress in preterm infants

Design

Clinical trial including two-arm parallel-group, randomized, with 20 patients, single blinded

Settings and conduct

This study was performed on preterm patients under 35 weeks in the neonatal intensive care unit of Amir Al-Momenin Hospital in Semnan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age between 25 to 35 weeks; Moderate to severe respiratory distress syndrome. Exclusion criteria: Patients with congenital anomalies; Patients needed endotracheal intubation.

Intervention groups

First intervention group: Nasal Continuous Positive Airway Pressure group; These infants underwent non-invasive ventilation Continuous Positive Airway Pressure using Bi nasal prong, Bubble Continuous Positive Airway Pressure, hot and humid airflow, and blender. Continuous Positive Airway Pressure was started with 5 cmH2O to keep the Saturation between 90 to 94 percent. Second Intervention group: Nasal high-frequency oscillation group, These infants underwent non-invasive mechanical ventilation using CNO devices for Medin company and Bi nasal prong and using oscillation and periodic opening and closing of the air outlet valve. Ventilation started by using CPAP with 5 cmH2O, frequency of 10 Hz, and oscillation that started with 5. At the eginning of ventilation, visible vibration of the upper chest was noted. It was started to keep the Saturation between 90 to 94 percent.

Main outcome variables

O2 therapy and O2 therapy time; MV (mechanical ventilation) and its duration and age of infants while MV; Apnea and age of infants at that time; surfactant and age of infants while that time; Pneumothorax and age of infants at that time;

General information

Reason for update

Acronym

Nasal Continuous positive Airway Pressure (NCPAP); Nasal high-frequency oscillation(NHFO)

IRCT registration information

IRCT registration number: **IRCT20201222049795N1**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **retrospective**

Last update: **2021-01-09, 1399/10/20**
Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Maryam Jandaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-30, 1399/07/09

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of Nasal Continuous Positive Airway Pressure (NCPAP) vs Nasal high-frequency oscillation(NHFO) in the treatment of respiratory distress in preterm infants

Public title

A comparison of the effect of Nasal Continuous Positive Airway Pressure (NCPAP) vs Nasal high-frequency oscillation(NHFO) in the treatment of respiratory distress in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 25 to 35 weeks Moderate to severe respiratory distress syndrome

Exclusion criteria:

Patients with congenital anomalies Patients needed endotracheal intubation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control with 10 members using block randomization with block sizes of 2. Randomized permutation blocks (block 2). Excel software rand function was used for randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are infants and it will be impossible for them to explain the method, treatment groups, and how to randomize; Therefore, participants will not be aware of the type of intervention received and are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University-Shahrood Branch

Street address

No.256, Amitis Apartment, Shahid Qods Ave, Bagh Ferdos Ave, Semnan

City

Shahrood

Province

Semnan

Postal code

3514618563

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1399.025

Health conditions studied

1

Description of health condition studied

Neonatal respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

preterm infants

Timepoint

Determining premature infants at the beginning of the study

Method of measurement

By measuring gestational age between 25 to 35 weeks

2

Description

respiratory distress

Timepoint

At the beginning of the study

Method of measurement

Using medical examinations

Secondary outcomes

1

Description
O2 Therapy
Timepoint
at any time interval of study If it's needed
Method of measurement
Using medical examinations

2

Description
O2 Therapy time
Timepoint
While O2 Therapy
Method of measurement
Counting the days of oxygen therapy

3

Description
invasive mechanical ventilation
Timepoint
at any time interval of study If it's needed
Method of measurement
If the infant does not respond to non-invasive mechanical ventilation

4

Description
Duration of using mechanical ventilation
Timepoint
While using mechanical ventilation
Method of measurement
Counting the days of using mechanical ventilation and Using the data collection form

5

Description
The infant's age at the time of use of mechanical ventilation
Timepoint
While using mechanical ventilation
Method of measurement
Age is calculated based on hours and Using the data collection form

6

Description
Apnea
Timepoint
At any time of apnea During or after being placed under the studied devices
Method of measurement
By observing the infant's breathing measuring devices

7

Description
The infant's age at the time of apnea
Timepoint
At any time of apnea
Method of measurement
Age is calculated based on hours and Using the data collection form

8

Description
surfactant
Timepoint
At any time of study if necessary
Method of measurement
Based on the physician's opinion and when there is no progress in the infant's respiratory recovery

9

Description
Age of infants at surfactant indication
Timepoint
At the time of surfactant indication
Method of measurement
Age is calculated based on hours and Using the data collection form

10

Description
Pneumothorax
Timepoint
During or after being placed under the studied devices
Method of measurement
By imaging and examination

11

Description
Age of infant's at the pneumothorax incidence
Timepoint
At the time of pneumothorax incidence
Method of measurement
Age is calculated based on hours and Using the data collection form

12

Description
IVH (Intra ventricular hemorrhage)
Timepoint
During or after being placed under the studied devices
Method of measurement
imaging

13

Description
Age of infant's at intraventricular hemorrhage
Timepoint
At the time of intraventricular hemorrhage
Method of measurement
Age is calculated based on hours and Using the data collection form

14

Description
CLD (Chronic Lung Disease)
Timepoint
after being placed under the studied devices
Method of measurement
imaging and examination

Intervention groups

1

Description
First intervention group: Nasal Continuous Positive Airway Pressure group; These infants underwent non-invasive ventilation Continuous Positive Airway Pressure using Bi nasal prong, Bubble Continuous Positive Airway Pressure, hot and humid airflow, and blender. Continuous Positive Airway Pressure was started with 5 cmH2O to keep the Saturation between 90 to 94 percent.
Category
Treatment - Devices

2

Description
Second Intervention group: Nasal high-frequency oscillation group, These infants underwent non-invasive mechanical ventilation using CNO devices for Medin company and Bi nasal prong and using oscillation and periodic opening and closing of the air outlet valve. Ventilation started by using CPAP with 5 cmH2O, frequency of 10 Hz, and oscillation that started with 5. At the beginning of ventilation, visible vibration of the upper chest was noted. It was started to keep the Saturation between 90 to 94 percent.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al_Momenin hospital
Full name of responsible person
Dr. Navid Danai
Street address
Amir Al_Momenin hospital, Mostafa Khomeini Blvd, Madar Square
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Email
amir.hospital@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Parviz Kokhaei
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Semnan
Postal code
35147-99442
Phone
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Fax
+98 23 3344 8999
Email
info@semnan.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Islamic Azad University
Full name of responsible person
Maryam Jandaghi
Position
Medical intern
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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