

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 beginning 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)

Phone

+98 23 3332 3194

Email address

m.jandaghi73@gmail.com

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

City

Semnan

Province

Semnan

Postal code

35197-34731

Phone

+98 23 3346 0055

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

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

35147-99442

Phone

+98 23 3344 1022

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

Street address

No 265, Bagh Ferdos Ave, Shahid Ghods Ave, Amitis Apartment

City

Semnan

Province

Semnan
Postal code
3514618563
Phone
+98 23 3332 3194
Fax
Email
M.Jandaghi73@gmail.com

Person responsible for scientific 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
Street address
No 265, Bagh Ferdos Ave, Shahid Ghods Ave, Amitis Apartment
City
Semnan
Province
Semnan
Postal code
3514618563
Phone
+98 23 3332 3194
Fax
Email
M.Jandaghi73@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person

Maryam Jandaghi
Position
Medical intern
Latest degree
Bachelor
Other areas of specialty/work
Pediatrics
Street address
No 265, Bagh Ferdos Ave, Shahid Ghods Ave, Amitis Apartment
City
Semnan
Province
Semnan
Postal code
3514618563
Phone
+98 23 3332 3194
Fax
Email
M.Jandaghi73@gmail.com

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