

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Efficacy of continuous positive oscillatory nasal airway pressure versus continuous positive nasal airway pressure in neonates with 28-34 weeks of gestational age with respiratory distress syndrome: A randomized controlled trial

Protocol summary

Summary

The aim of this study is to investigate whether Oscillatory NCPAP, in comparison to NCPAP, can reduce the need for intubation and mechanical ventilation in preterm neonates with suspected RDS. In this single center, not blinded and randomized controlled trial, based on a random number table, 128 neonates, at 28-34 gestational weeks, who had respiratory distress syndrome and a Silverman-Anderson retraction Score of 6-7, admitted to Imam Khomeini Hospital's NICU during 2016 (64 in each group) were included. We use Oscillatory NCPAP (cno ncpap driver) with Peak end expiratory pressure (PEEP) of 4-6 cm of water, fraction of inspired oxygen (FiO2) equal to 0.4, frequency of 3 Hz and amplitude of 3 mv and NCPAP (sindi ncpap driver) with Peak end expiratory pressure (PEEP) 4-6 cm of water, fraction of inspired oxygen (FiO2) equal to 0.4. Babies were excluded if there was congenital malformation, severe cardiovascular instability and severe asphyxia or if parents had no consent. The primary outcome was to assess the need for intubation within 72 hours of life. The secondary outcomes were complications for example intra ventricular hemorrhage, pneumothorax and feed intolerance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111930964N1**
Registration date: **2016-12-30, 1395/10/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-30, 1395/10/10

Registrant information

Name

Shiva Bashirnejadkhabaz

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2016-06-05, 1395/03/16

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of continuous positive oscillatory nasal airway pressure versus continuous positive nasal airway pressure in neonates with 28-34 weeks of gestational age with respiratory distress syndrome: A randomized controlled trial

Public title

Study of two non-invasive ventilation methods in the treatment of acute respiratory distress syndrome of infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preterm infants at gestational age of 28 to 34 weeks; weight between 1000 and 2000 grams; respiratory distress syndrome; Silverman-Anderson retraction score 6 - 7. Exclusion criteria: Congenital malformation; cardiac disease; severe asphyxia (Apgar score ≤ 3 at 1 and 5 minute or pH ≤ 7.12); parents' unwillingness to participate in the study.

Age

To 1 day old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 128

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized based on a random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Ahvaz Jundishapur University of Medical Sciences

Street address

The main door of Ahvaz Jundishapur University of Medical Sciences and Health Services, opposite the Khuzestan Water and Electricity Authority (five storeys), Golestan highway, Ahvaz

City

Ahvaz

Postal code

1579461357

Approval date

2016-06-05, 1395/03/16

Ethics committee reference number

IR.AJUMS.REC.1395.162

Health conditions studied

1

Description of health condition studied

respiratory distress syndrome in new borns

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Non-invasive ventilatory failure

Timepoint

During first 72 hours of birth

Method of measurement

A questionnaire was used to investigate the noninvasive ventilation failure within first 72 hours of birth in which data were collected based on observation and ABG. The failure criteria were met by at least 1 of the following: pH ≤ 7.20 and PaCO₂ ≥ 60 mm Hg, PaO₂ ≤ 50 mm Hg with a fraction of inspired oxygen ≥ 0.6 or respiratory distress increase, recurrent apnea with ≥ 3 episodes per hour associated with bradycardia, a single episode of apnea that required bag and mask ventilation.

Secondary outcomes

1

Description

Milk intolerance rate

Timepoint

Within admission period

Method of measurement

questionnaire

2

Description

Pneumothorax

Timepoint

Within first 72 h

Method of measurement

CXR

3

Description

IVH

Timepoint

At the end of first and fourth week or at the time of symptom incidence.

Method of measurement

brain sonography

Intervention groups

1

Description

Intervention 1: Eligible newborns were randomly allocated to the 'Oscillatory NCPAP' group. For this purpose, cno ncpap device (made in Germany) was employed. Using this device, nasal continuous positive airway pressure with vibration was given to the patient. INSURE (intubation, surfactant treatment and extubation) technique would have been used if the patient had needed PEEP ≥ 5 cm/H₂O and Fio₂ $\geq 40\%$. The orogastric tube was kept open and suspended from the top wall of the incubator to decompress the stomach. Pulse oximeter saturation, respiratory rate and heart rate were continuously monitored. Blood pressure was measured at least every 6 hours. ABG was performed after 30 min of starting respiratory support, then, at least every 6 hours in first 24 hours and every 8 hours in next 24 h and as indicated. We used oscillatory NCPAP with PEEP 4-6 cm of water, fraction of inspired oxygen (Fio₂) of 0.4, frequency of 3 HZ and amplitude of 3 cm H₂O. Maximum permissible PEEP was 8 cm and maximum permissible Fio₂ was 0.6. Maximum permissible frequency and amplitude were at the time that we observed oscillation on chest wall (Maximum frequency of 5 HZ and amplitude of 7 cm H₂O). Settings was adjusted based on arterial blood gases (ABG) and clinical parameters. Targeted saturation was $\geq 90\%$.

Category

Treatment - Other

2

Description

Intervention 2: Eligible newborns were randomly allocated to the 'NCPAP' group. For this purpose, sindi ncpap device (made in Germany) was employed. Using this device, nasal continuous positive airway pressure was given to the patient. INSURE (intubation, surfactant treatment and extubation) technique would have been used if the patient had needed PEEP ≥ 5 cm/H₂O and Fio₂ $\geq 40\%$. The orogastric tube was kept open and suspended from the top wall of the incubator to decompress the stomach. Pulse oximeter saturation, respiratory rate and heart rate were continuously monitored. Blood pressure measured at least every 6 h. ABG was performed after 30 min of starting respiratory support, then, at least every 6 h in first 24 h and every 8 h in next 24 h and as indicated. We used NCPAP with PEEP equal to 4-6 cm of water and fraction of inspired oxygen (Fio₂) equal to 0.4. Maximum permissible target was 8 cm for PEEP and 0.6 for Fio₂. Settings was adjusted based on arterial blood gases (ABG) and clinical parameters. Targeted saturation was $\geq 90\%$.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Intensive Care Unit of Imam Khomeini Hospital

Full name of responsible person

Shiva Bashirnejadkhabaz

Street address

Imam Khomeini Hospital, Azadegan street, Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research and technology of Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Behzad SharifMakhmalzadeh

Street address

Vice Chancellor for research and technology of Ahwaz Jundishapur University of Medical Sciences, Daneshgahi Settlements, Ahwaz

City

Ahwaz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research and technology of Ahwaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Shiva Bashirnejad khabaz

Position

Neonatology subspecialty trainee

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Arash Malekian

Position

Neonatologist

Other areas of specialty/work**Street address**

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Position

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Other areas of specialty/work**Street address**

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Fax**Email**

bashirnejad.sh@ajums.ac.ir;

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty