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
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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 ≥ 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 ≥ 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 ≥ 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 ≥ 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

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Behzad SharifMakhmalzadeh

Street address

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

City

Ahvaz

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 Ahvaz 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

Ahvaz 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

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Arash Malekian

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Neonatologist

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Other areas of specialty/work

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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