Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison the effect of nasal mask and nasal prong on duration of nasal CPAP support and other complications of prematurity in preterm newborns affiliated from RDS

Protocol summary

Study aim
Comparison of mean level of CPAP؛ mean number of surfactant administration؛ Need for mechanical ventilation in first 72 hours؛ Incidence of air leak syndrome؛ Incidence of BPD؛ mean Duration of N-CPAP؛ mean duration of hospitalization and incidence of nasal trauma in preterm newborns affiliated from RDS receiving N-CPAP with mask and prong

Design
Two arm parallel group randomised trial with outcome assessment on 196 preterm newborns

Settings and conduct
The study was conducted on preterm newborns affiliated from RDS in hospitals dependent to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria
This study was a randomized clinical trial on 196 preterm newborns with gestational age between 28 to 34 week affiliated with RDS hospitalized in centers dependent to Isfahan University of Medical Sciences and need for respiratory support via NCPAP.

Intervention groups
Newborns in first group receive NCPAP in supine position via nasal mask and surfactant administrate using INSURE technique according to the definitive criteria. newborns in second group receive NCPAP in same position via nasal prong. In second group the manner of surfactant administration and weaning are same as first group.

Main outcome variables
Duration of NCPAP؛ CPAP level؛ Duration of hospitalization؛ Need for mechanical ventilation؛ Incidence of BPD؛ Incidence of air leak syndrome؛Number of surfactant administration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150423021910N8**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **prospective**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date
2022-02-11, 1400/11/22

Registrant information

Name
Behzad Barekatain

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison the effect of nasal mask and nasal prong on duration of nasal CPAP support and other complications of prematurity in preterm newborns affiliated from RDS

Public title
Evaluation of appropriate for delivering positive expiratory pressure in preterm newborns affiliated from RDS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age between 28 to 34 W Affiliated from RDS Mother received one course of steroid therapy before delivery
Exclusion criteria:
Existence of Congenital Heart Disease Existence of Perinatal Asphyxia(umbilical pH less than 7/2 and bicarbonate less than 12) Existence of maternal chorioamnionitis
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **196**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is simple and individuals. table of random numbers use to randomization. at first one row and one column selected randomly and conflux point of row and column was consider as initial point of sampling. then top down even numbers and odd numbers accrue to first and second groups respectively. for allocation concealment 196 envelopes prepare and random numbers register. after closure of envelopes, we put those into the box. according to the order of patients one of the envelopes open and patients allocate to case or control groups.
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
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Hezarjerib bolvar, Isfahan University of Medical Sciense
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-08-07, 1400/05/16
Ethics committee reference number
IR.MUI.MED.REC.1400.364

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Duration of CPAP
Timepoint
Hour
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Mean of CPAP
Timepoint
During study
Method of measurement
CPAP desktop

2

Description
Duration of hospitalization
Timepoint
Daily
Method of measurement
Questionnaire

3

Description
Need for mechanical ventilation

Timepoint
During study
Method of measurement
Clinical examination

4

Description
Bronchopulmonary dysplasia
Timepoint
During study
Method of measurement
Clinical examination

5

Description
Pneumothorax
Timepoint
During study
Method of measurement
Chest X ray

6

Description
The number of surfactant administration
Timepoint
During study
Method of measurement
Clinical examination

7

Description
Nasal trauma
Timepoint
During study
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group: The newborns in first group put in supine position and respiratory support was established with nCPAP (Bubble CPAP Infant Delivery System, Fisher & Paykel, Auckland, New Zealand) with nasal mask; at first CDP equal to 6-8 cmH2O and Fio2=30% was administrated. If the newborn needed inspiratory oxygen fraction of higher than 40% to maintain oxygen saturation in the right hand at 90–95% for more than 1 hour, the newborn would receive 200 mg/kg of Crusorf per INSURE method. If the newborn's need for the inspiratory oxygen fraction of higher than 40% was consistent to maintain the oxygen saturation level in an acceptable range,after 12 h from the last administration of surfactant, Crusorf (100 mg/kg) would be administered again, and as necessary, the full course of treatment (maximum 3 dose) would be observed. after stabilization under CPAP for more than 12 hour, CDP decrease every 4 hour and in the setting as CDP=4 cmH2O and FiO2<25% newborn wean from nCPAP.
Category
Treatment - Devices

2

Description
Intervention group: The newborns in second group put in supine position and respiratory support was established with nCPAP (Bubble CPAP Infant Delivery System, Fisher & Paykel, Auckland, New Zealand) with nasal prong; at first CDP equal to 6-8 cmH2O and Fio2=30% was administrated. If the newborn needed inspiratory oxygen fraction of higher than 40% to maintain oxygen saturation in the right hand at 90–95% for more than 1 hour, the newborn would receive 200 mg/kg of Crusorf per INSURE method. If the newborn's need for the inspiratory oxygen fraction of higher than 40% was consistent to maintain the oxygen saturation level in an acceptable range,after 12 h from the last administration of surfactant, Crusorf (100 mg/kg) would be administered again, and as necessary, the full course of treatment (maximum 3 dose) would be observed. after stabilization under CPAP for more than 12 hour, CDP decrease every 4 hour and in the setting as CDP=4 cmH2O and FiO2<25% newborn wean from nCPAP.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
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2

Recruitment center
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more informations
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available