

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Barekatin

Name of organization / entity

Isfahan University of Medical Sciences

Country

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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		Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences	
Public title	Evaluation of appropriate for delivering positive expiratory pressure in preterm newborns affiliated from RDS	Street address	Hezarjerib bolvar, Isfahan University of Medical Science
Purpose	Treatment	City	Isfahan
Inclusion/Exclusion criteria		Province	Isfahan
Inclusion criteria:	Gestational age between 28 to 34 W Affiliated from RDS Mother received one course of steroid therapy before delivery	Postal code	8174673461
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	Approval date	2021-08-07, 1400/05/16
Age	From 1 day old to 30 days old	Ethics committee reference number	IR.MUI.MED.REC.1400.364
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 196	Respiratory Distress Syndrome	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
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.	ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Respiratory distress syndrome of newborn	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		Duration of CPAP	
Secondary Ids		Timepoint	
empty		Hour	
Ethics committees		Method of measurement	
1		Questionnaire	
Ethics committee		Secondary outcomes	
Name of ethics committee		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

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

shahid beheshti hospitals

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Sponsors / Funding sources

1

Sponsor

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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