Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Ventilators Work of Breath Based on Constant flow nasal CPAP through Pressure Limited and Electronic Feedback Pressure Control Mechanisms in the Treatment of Respiratory Distress Syndrome in Neonates Weighing 1000 grams

Protocol summary

Study aim
The present study aims at improving the quality of respiratory support in neonates with RDS.

Design
Clinical trial with randomized intervention and control groups, 70 neonates (35 participants in each group)

Settings and conduct
The present study was conducted in Alzahra Hospital in Isfahan, Iran using servo-i and Christina ventilators.

Participants/Inclusion and exclusion criteria
The inclusion criterion was neonates weighing 1000 grams with respiratory distress syndrome (Tachypnea, Intercostal retraction, nasal flaring, granting, needing inspired oxygen fraction higher than 21%) and the exclusion criteria were congenital anomaly and perinatal asphyxia (5-minute apgar score between 0 and 3, umbilical cord ph less than 7 and umbilical cord bicarbonate less than 12 mEq/Lit).

Intervention groups
Neonates in the PC-nCPAP group (intervention group) experienced respiratory support using servo-i ventilator. Neonates in the PL-nCPAP group (control group) experienced respiratory support using Christina ventilator.

Main outcome variables
1- Work of Breath of Ventilator 2- Duration of Non-invasive ventilation 3- Rapid Shallow Breathing (RSB) index 4- Chronic Lung Disease (CLD) 5- Intra-Ventricular Hemorrhage 6- Pneumothorax 7- Surfactant Administration 8- Death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120728010430N8**
Registration date: **2019-05-12, 1398/02/22**
Registration timing: **retrospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **0**

Registration date
2019-05-12, 1398/02/22

Registrant information

Name
Alireza Sadeghnia
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-08-01, 1394/05/10

Expected recruitment end date
2018-02-01, 1396/11/12

Actual recruitment start date
2015-08-01, 1394/05/10

Actual recruitment end date
2018-02-01, 1396/11/12

Trial completion date
2018-02-01, 1396/11/12

Scientific title
Comparison of Ventilators Work of Breath Based on Constant flow nasal CPAP through Pressure Limited and

Electronic Feedback Pressure Control Mechanisms in the Treatment of Respiratory Distress Syndrome in Neonates Weighing 1000 grams

Public title
Investigating CPAP in Treatment of RDS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
neonates weighing 1000 grams with respiratory distress syndrome (Tachypnea, Intercostal retraction, nasal flaring, granting, needing inspired oxygen fraction higher than 21%)
Exclusion criteria:
congenital anomaly and perinatal asphyxia (5-minute apgar score between 0 and 3, umbilical cord ph less than 7 and umbilical cord bicarbonate less than 12 mEq/Lit)
Age
From **1 day** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **35**
neonates weighing 1000 grams with respiratory distress syndrome admission in NICU in Alzahra Hospital and Shahid Beheshti Hospital associated with Isfahan University of Medical Sciences from August, 2015 to February, 2018
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Neonates whose first file number digit was an even number were put in PC-nCPAP group and those with an odd first file number digit were grouped as PL-nCPAP.
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
Ethics committee of University of Medical Sciences of Isfahan
Street address
Hezar Jarib St., Azadi Sq., Isfahan, Iran
City
Isfehan
Province
Isfehan
Postal code
8174673461
Approval date
2016-04-20, 1395/02/01
Ethics committee reference number
IR.MUI.REC.1395.3.075

Health conditions studied

1

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

Primary outcomes

1

Description
The average Work of Breath in PC- nCPAP and PL- nCPAP
Timepoint
Every 6 hours
Method of measurement
expiratory tidal volume multiplied by dynamic pressure

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Neonates in PL-nCPAP group were supported with nCPAP respiratory support using Nasal prong Argyle (Covidien, Mansfield, USA) with the aid of Christina ventilator (Stephan, Medizintechnik, Hamburg, Germany). The primary CDP level was set as 6 cmH2O and FiO2=30%. The neonates who needed an inhaled oxygen fraction higher than 40% in order to keep oxygen saturation level at 90%-95% in their right hands received 100 mg/kg of Survanta using INSURE method. Then, if the neonates' need of inhaled oxygen fraction higher than 40% was kept constant at acceptable levels, Survanta was administered again 6 hours after administration of the previous surfactant dose, which continued maximally for 4 doses. CBG (Capillary Blood Gas) was performed before and after surfactant administration and then continued every 12 hours and, based on that, related mechanical ventilation

management alterations were made. Patients with any of the following conditions would be discontinued from non-invasive ventilation and would then undergo intubation and invasive ventilation:• Despite a CDP of 8 cmH2O and FiO2≤75%, inability to keep oxygen saturation level at 90% to 95% in their right hands. Gasometric indices in CBG showing respiratory failure (pH<7.2 & PCO2>65 mmHg). More than 3 times of apnea per hour requiring ventilation using a bag and a mask. During respiratory management, in instances when a neonate's need for fraction of inspirated oxygen in levels lower than 50% was kept constant for more than 4 hours, CDP gradually dropped 1 to 2 cmH2O to keep O2Sat at an acceptable range. At CDP=4 cmH2O and Fio2<30%, the neonate was weaned from respiratory support.

Category

Treatment - Devices

2

Description

Intervention group: Neonates in PC-nCPAP group were provided with nCPAP respiratory support including Nasal prong Argyle (Covidien, Mansfield, USA) and Servo-i ventilator (Maquet, Solna, Sweden). Servo-I was equipped with a non-invasive ventilation software program and the users selected 'Non-Invasive Ventilation' and 'nCPAP' prior to activating ventilation. The primary CDP level was set as 6 cmH2O and FiO2=30%. The neonates who needed an inhaled oxygen fraction higher than 40% in order to keep oxygen saturation level at 90%-95% in their right hands received 100 mg/kg of Survanta using INSURE method. Then, if the neonates' need of inhaled oxygen fraction higher than 40% was kept constant at acceptable levels, Survanta was administered again 6 hours after administration of the previous surfactant dose, which continued maximally for 4 doses. CBG (Capillary Blood Gas) was performed before and after surfactant administration and then continued every 12 hours and, based on that, related mechanical ventilation management alterations were made. Patients with any of the following conditions would be discontinued from non-invasive ventilation and would then undergo intubation and invasive ventilation:• Despite a CDP of 8 cmH2O and FiO2≤75%, inability to keep oxygen saturation level at 90% to 95% in their right hands. Gasometric indices in CBG showing respiratory failure (pH<7.2 & PCO2>65 mmHg). More than 3 times of apnea per hour requiring ventilation using a bag and a mask. During respiratory management, in instances when a neonate's need for fraction of inspirated oxygen in levels lower than 50% was kept constant for more than 4 hours, CDP gradually dropped 1 to 2 cmH2O to keep O2Sat at an acceptable range. At CDP=4 cmH2O and Fio2<30%, the neonate was weaned from respiratory support.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Alireza Sadeghnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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
Esfahan University of Medical Sciences

Full name of responsible person
Alireza Sadeghnia

Position
Associate Professor

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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

Title and more details about the data/document
Calculation method for primary and secondary objectives

When the data will become available and for how long
April, 2019 to April 2020

To whom data/document is available
Medical researchers in the field of neonatology

Under which criteria data/document could be used
No limitations exist on data analysis.

From where data/document is obtainable
E-mailing the corresponding author

What processes are involved for a request to access data/document
No limitations exist.

Comments