

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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, grunting, 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

Country

Iran (Islamic Republic of)

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+98 31 3335 1777

Email address

sadeghnia@med.mui.ac.ir

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, grunting, 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

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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 Surfactant using INSURE method. Then, if the neonates' need of inhaled oxygen fraction higher than 40% was kept constant at acceptable levels, Surfactant 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 inspired 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 Surfactant using INSURE method. Then, if the neonates' need of inhaled oxygen fraction higher than 40% was kept constant at acceptable levels, Surfactant 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 inspired 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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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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