Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Therapeutic effect of Nasal high frequency ventilation(NHFV) versus nasal continuous positive airway pressure(NCPAP) for respiratory distress syndrome in newborn with birth with more than 1000 gram and more than 30 week of gestational age

Protocol summary

Summary

Premature infants with respiratory distress syndrome (RDS) usually require respiratory support. Due to the complications of intubation and mechanical ventilation, in the last decade, attempts have been made to use non-invasive methods in management of these patients. One of the most commonly used non-invasive methods is nasal CPAP. However, some neonate with this therapeutic approach also developed respiratory failure and they need more respiratory support. So far, the beneficial effects of high frequency ventilators have been shown in management of RDS, However, its effect on the nasal method has been less studied. In this study we evaluate the efficacy of nasal high frequency ventilation (NHFV) in reducing the duration of respiratory distress compared with nasal continuous positive airway pressure (NCPAP) in RDS. In this randomized-prospective study, 62 infants with a gestational age ≥ 30 weeks and birth weight ≥ 1000 g with RDS and spontaneous breathing since birth will randomized to either NHFV (n = 31) or NCPAP (n = 31). Infant were excluded if there was any of the following cases: major congenital anomalies; asphyxia and cyanotic congenital heart disease. The primary outcome is the reduction of the duration of respiratory distress. Secondary outcome are the duration and level of oxygen supplementation, the incidence of complications such as pneumothorax, necrotizing enter colitis, sepsis and respiratory failure requiring intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062734782N1**
Registration date: **2017-09-09, 1396/06/18**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-09-09, 1396/06/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effect of Nasal high frequency ventilation(NHFV) versus nasal continuous positive airway pressure(NCPAP) for respiratory distress syndrome in newborn with birth with more than 1000 gram and more than 30 week of gestational age

Public title
The efficacy of nasal high frequency ventilation in treatment of neonatal respiratory syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: premature and term neonate; more than 1000 gram and 30 weeks of gestational age; spontaneous breathing; respiratory distress syndrome symptoms required treatment Exclusion criteria: major congenital anomaly; diaphragmatic hernia; cyanotic heart disease; intrauterine growth retardation; asphyxia
Age
To **1 month** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Isfahan University of Medical Sciences
Street address
Hezar-Jerib St.,Isfahan University of Medical Sciences
City
Isfahan
Postal code
8184757851
Approval date
2017-06-21, 1396/03/31
Ethics committee reference number
IR.MUI.REC.1396.3.336

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
The duration of non-invasive support
Timepoint
Every hour
Method of measurement
hourly NICU recorded sheets

Secondary outcomes

1

Description
pulmonary hemorrhage
Timepoint
hourly
Method of measurement
physical exam and chest xray if needed

2

Description
narcotizing enterocolitis (NEC)
Timepoint
Daily
Method of measurement
Daily recorded sheets and daily physical exam and abdominal xray if needed

3

Description
Intraventricular hemorrhage (IVH)
Timepoint
at the 3rd and 7th days after birth
Method of measurement
brain sonography

4

Description
respiratory failure and intubation
Timepoint
continuously every hour during non-invasive respiratory support
Method of measurement
NICU record sheets

5

Description
pnuemothorax
Timepoint

continuously every hour during non-invasive respiratory support

Method of measurement

NICU record sheets

6

Description

chronic lung disease

Timepoint

4 weeks after birth

Method of measurement

NICU record sheets

7

Description

patent ductus arteriosus

Timepoint

Daily physical exam

Method of measurement

Daily recorded sheets

8

Description

time to full enteral feeding

Timepoint

Daily till full feeding

Method of measurement

Daily recorded sheets

Intervention groups

1

Description

Infants with respiratory distress syndrome according of inclusion criteria randomized to NCPAP (control group) will treat with nasal CPAP shortly after birth. CPAP pressure will consider as 6-7 cmH20 and FIO2 adjust to maintain o2 saturation of patients between 89-95%. Surfactant (200mg/kg first dose and then 100mg/kg the next doses, curosurf (Chiesa pharmaceuticals, Parma, Italy) will administrate if patients need FIo2 > 35% to keep desired SPO2. If FIO2 reach to under 30% patient wean to Humidified High Flow Nasal Cannula (HHFNC) and when FIO2 reach to 21% and respiratory distress improved, HHFNC also will discontinued. Surfactant administrate as INSURE method. NCPAP failure defined as apnea or PH<7.2 and Pco2 >60 mmHg.

Category

Treatment - Devices

2

Description

Infants with respiratory distress syndrome according of inclusion criteria randomized to NHFV (control group) will treat with nasal high frequency ventilator [Fabian, Acutronic Medical Systems AG, based in Hirzel (Zurich, Switzerland)], shortly after birth. Pmean pressure will consider as 8 cmH20 and FIO2 adjust to maintain O2 saturation of patients between 89-95%. Initial frequency will set as 10 Hz. Amplitude will set based the vibration of upper chest wall and the neck of patients and increased to maximum 20mmHg. Surfactant (200mg/kg first dose and then 100mg/kg the next doses, curosurf (Chiesa pharmaceuticals, Parma, Italy) will administrate if patients need FIo2 > 35% to keep desired SPO2. If FIO2 reach to under 30% patient wean to Humidified High Flow Nasal Cannula (HHFNC) and when FIO2 reach to 21% and respiratory distress improved, HHFNC also will discontinued. Surfactant administrate as INSURE method. NCPAP failure defined as apnea or PH<7.2 and Pco2 >60 mmHg.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Ramin Iranpour

Street address

sofeh bolvar

City

Isfahan

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Ramin Iranpour

Street address

Motahari street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Bahram Nasr

Street address

Hezar-jerib street

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Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

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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