

# 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  $\geq 30$  weeks and birth weight  $\geq 1000$  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

###### Name

Ramin Iranpour

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3386 8247

###### Email address

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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**

pneumothorax

**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 cmH<sub>2</sub>O and FIO<sub>2</sub> adjust to maintain O<sub>2</sub> 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 FIO<sub>2</sub> > 35% to keep desired SPO<sub>2</sub>. If FIO<sub>2</sub> reach to under 30% patient wean to Humidified High Flow Nasal Cannula (HHFNC) and when FIO<sub>2</sub> 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 Pco<sub>2</sub> >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 cmH<sub>2</sub>O and FIO<sub>2</sub> adjust to maintain O<sub>2</sub>

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 FIO<sub>2</sub> > 35% to keep desired SPO<sub>2</sub>. If FIO<sub>2</sub> reach to under 30% patient wean to Humidified High Flow Nasal Cannula (HHFNC) and when FIO<sub>2</sub> 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 Pco<sub>2</sub> >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**

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Bahram Nasr

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Hezar-jerib street

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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**

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*

Isfahan

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Isfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

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Isfahan University of Medical Sciences

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Dr Ramin Iranpour

**Position**

Neonatologist/Associate Professor

**Other areas of specialty/work****Street address**

Mardavij avenue, Resalat Jonobi, Number16

**City****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*