# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Therapeutic effect of heated, humidified, high-flow nasal cannula (HHHFNC) and Nasal intermittent mandatory ventilation (NIMV) as initial therapy of respiratory distress syndrome (RDS) in very Low Birth Weight (VLBW) Infants

## Protocol summary

**Summary**

Premature babies (especially VLBW) respiratory distress syndrome (RDS) may require respiratory support .Now is general agreement that the use of mechanical ventilation due to high to minimize side effects. For this reason; various methods of non-invasive ventilation (NRS) to reduce the use of mechanical ventilation is evolving and developing. The main advantage of this novel therapeutic approaches to reduce the rate of neonatal endotracheal tube intubation is. Infants were excluded if there was any of the following cases :Major congenital anomalies ;asphyxia and congenital cyanotic heart disease .In this study very low brith weight (BW<1500gr) with respiratory distress were considered eligible .Thirty-five infants were randomly assigned early NIMV and thirty-five comparable infants to early HHHFNC .Surfactant were given; when Fio2 requirement was of more than 30% .Shown that the application of continuous positive airway pressure to the airway through the nose (NCPAP) is one of the treatment options RDS in premature newborns that as an effective method to reduce the use of mechanical ventilation in a fairly large number of newborns preterm RDS is. Another method of treatment NRS nasal intermittent mechanical ventilation (NIMV) that the use of NIMV and HHHFNC post extubation and apea of prematurity are more effective than NCPAP. NIMV in the treatment of premature infants with RDS used. But do NIMV use as an initial treatment for RDS is controversial. In this way; despite the use of endotracheal intubation ventilation device can not be used and from nasal pronge.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016052510026N7**
Registration date: **2017-07-08, 1396/04/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-07-08, 1396/04/17

**Registrant information**

**Name**

Amir mohammad Armanian

**Name of organization / entity**

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Isfahan University of Medical Sciences

**Expected recruitment start date**

2017-01-09, 1395/10/20

**Expected recruitment end date**

2017-06-20, 1396/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Therapeutic effect of heated, humidified, high-flow nasal cannula (HHHFNC) and Nasal intermittent mandatory ventilation (NIMV) as initial therapy of respiratory distress syndrome (RDS) in very Low Birth Weight (VLBW) Infants

**Public title**
Therapeutic effect of heated, humidified, high-flow nasal cannula (HHHFNC) in respiratory distress syndrome
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: premature infants, weighing less than 1500 g and RDS symptoms requires treatment. Exclusion criteria: are major congenital anomalies; respiratory anomalies; orofacial malformations and cyanotic heart diseases.
**Age**
To **1 month** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **70**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double 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**
Isfahan University of Medical Sciences, Hezarjerib st.
**City**
Isfahan
**Postal code**
8184757851
**Approval date**
2016-07-20, 1395/04/30
**Ethics committee reference number**
IR.MUI.REC.1395.3.415

## 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 respiratory support
**Timepoint**
at the 3th and 7th days of life
**Method of measurement**
Daily recorded sheets

## Secondary outcomes

### 1

**Description**
Time to full enteral feeds
**Timepoint**
at the 3th, 7th and 15th days of life
**Method of measurement**
Daily recorded sheets

## Intervention groups

### 1

**Description**
For infants in early-NIMV group (non-synchronized mode), NIMV will set at peak inspiratory pressure (PIP) of 16 -20 cmH2O (according to infant’s birth weight and chest wall expansion), positive end expiratory pressure (PEEP) of 5 to 6 cmH2O, rate of 40- 50 breaths/min (according to PaCO2), inspiratory time (Ti) of 0.4 seconds and flow rate of 8 to 10 L/minute. Setting was adjusted according to arterial blood gases (ABG), clinical parameters and to maintain SPO2between 91% - 95%. Surfactant [(100 mg/kg per dose, Curosurf (Chiesa pharmaceuticals, Parma, Italy) or Survanta (Abbott laboratories, Illinois, USA)] was administered if studied neonates needed a fraction of inspired oxygen (FIO2) of >30% to keep the SPO2of > 91%. INSURE approach, only as rescue therapy, was used in both groups
**Category**
Treatment - Devices

### 2

**Description**
For infants in HHHFNC group, high flow was initiated with a flow of 2.5-3 L/minute by a short bi-nasal prongs.

Setting was adjusted according to arterial blood gases (ABG), clinical parameters and to maintain SPO2between 91% - 95%. Surfactant [(100 mg/kg per dose, Curosurf (Chiesa pharmaceuticals, Parma, Italy) or Survanta (Abbott laboratories, Illinois, USA)] was administered if studied neonates needed a fraction of inspired oxygen (FIO2) of >30% to keep the SPO2of > 91%. INSURE approach, only as rescue therapy, was used in both groups

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

NICU at Alzahra and Shahid Beheshti hospitals in Isfahan IRAN

**Full name of responsible person**

Dr. Amir Mohammad Armanian

**Street address**

Number 133, Shahid ansari alley, Saeb street, Isfahan,Iran Isfahan

**City**

Isfahan

### 2

**Recruitment center**

**Name of recruitment center**

NICU at Alzahra and Shahid Beheshti hospitals in Isfahan IRAN

**Full name of responsible person**

Dr. Amir Mohammad Armanian

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Number 133, Shahid ansari alley, Saeb street, Isfahan,Iran Isfahan

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.nasri

**Street address**

Isfahan University of Medical Sciences, Hezarjerib st.

**City**

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**

**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*

### 2

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.nasri

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**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*

## Person responsible for general inquiries

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## Person responsible for updating data

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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*