Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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

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Name of organization / entity

Isfahan University of Medical Sciences

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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

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

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Recruitment center

Name of recruitment center

NICU at Alzahra and Shahid Beheshti hospitals in Isfahan IRAN

Full name of responsible person

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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

Street address

Isfahan University of Medical Sciences, Hezarjerib st.

City

Isfahan

Grant name

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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

Person responsible for general inquiries

Contact

Name of organization / entity

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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