Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Therapeutic effect of NIMV and NCPAP as initial therapy of RDS in premature VLBW infants admitted in Alzahra and Shashid Beheshti hospitals of Isfahan.

Protocol summary

Summary

We interested on evaluation the effect of NIMV and NCPAP as the first treatment of RDS and then comparing the obtained results. Finally we hypothesized that initial treatment with NIMV in preterm neonates with RDS may obtain more favorable outcomes in terms of the duration of treatment and the endotracheal tube ventilation in comparison to 'early NCPAP'. In this single-center randomized control trial (RCT) study, infants who will born with a birth weight (BW) =<1500 gr (VLBW) and clinical evidence of respiratory distress will eligible for participation in the study. Infants will exclude if there is any of the following cases: major congenital anomalies, asphyxia, congenital cyanotic heart disease, cardiovascular instability, orofacial anomalies and consent refuse or not provide. Studied neonates will randomly allocate to initial treatment with either early-NIMV (NIMV group) or early-NCPAP (NCPAP group). 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. NCPAP will initiate on a continuous pressure of 5 to 6 cmH2O with a flow of 8 to 10 L/minute. Surfactant [(100 mg/kg per dose will administered if studied neonates, to keep the SPO2 of > 88% - 92%, need a fraction of inspired oxygen (FIO2) of > 30%. INSURE approach, only as rescue therapy, will use in both groups. Infants on NIMV will wean from a PIP of 14-15 cmH2O, PEEP 4-5 cmH2O, and FIO2 of < 30%, with acceptable clinical evidence and ABG. Infants on NCPAP will wean from a CPAP of 4 cmH2O and FIO2 of < 30%, with acceptable clinical evidence and ABG. After weaning, infants in both groups could be wean to Humidified High-Flow Nasal Cannula (HHFNC) at 2.5 -3 L/min. Efforts to wean the flow by as much as tolerated will make gradually. HHFNC will stop completely once infants will be able to maintain SPO2 between 88-92% in room air for at least more than 4 hours. The primary outcomes of the study are the effect of NIMV on need for intubation/endotracheal tube ventilation (e.g. failure of noninvasive respiratory support) within the first 48 h of study and on the duration of non-invasive respiratory support in each group. Presence of any or more of the following will regard as criteria for failure, in both groups: PH < 7.2 and PCo2 > 60, SPO2 of < 88% with a FIO2 of >= 70% , recurrent apnea > 3 times per hour requiring tactile stimulation and any sever apnea which need to bag and mask ventilation. Secondary outcomes are need to INSURE approach, the duration of dependency to oxygen, incidence of CLD, time to full enteral feeds, length of hospital stay, pneumothorax and other morbidity during the hospitalization such as intraventricular hemorrhage (IVH), patent ductus arteriosus (PDA).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021410026N4**
Registration date: **2014-04-09, 1393/01/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-09, 1393/01/20

Registrant information

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Recruitment status
Recruitment complete
Funding source
Isfahan University of Medical Sciences, Isfahan, Iran.

Expected recruitment start date
2012-11-21, 1391/09/01
Expected recruitment end date
2014-01-22, 1392/11/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Therapeutic effect of NIMV and NCPAP as initial therapy of RDS in premature VLBW infants admitted in Alzahra and Shashid Beheshti hospitals of Isfahan.

Public title
The effect of NIMV on premature infants
Purpose
Prevention
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 year** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **98**
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
Isfahan University of Medical Sciences, Hezarjerib st.
City
Isfahan
Postal code
8184757851
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
39222

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrom
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrom

Primary outcomes

1

Description
The effect of NIMV on need for intubation/endotracheal tube ventilation
Timepoint
Within the first 48 h of life
Method of measurement
Clinical evidence of respiratory distress & ABG

2

Description
The duration of non-invasive respiratory support
Timepoint
Within the first 48 h of study
Method of measurement
Clinical evidence of respiratory distress $ ABG

Secondary outcomes

1

Description
Needed to surfactant
Timepoint
During first 48 h of life

Method of measurement
Daily recorded sheets

2

Description
Duration of dependency to oxygen
Timepoint
First month of life
Method of measurement
Daily recorded sheets

3

Description
Time to full enteral feeds
Timepoint
During first month of life
Method of measurement
Daily recorded sheets

4

Description
Hospitalization time
Timepoint
During first month of life
Method of measurement
Daily recorded sheets

5

Description
Pneumothorax
Timepoint
During first month 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
Category
Treatment - Devices

2

Description
For infants in early-NCPAP group, NCPAP will initiate on a continuous pressure of 5 to 6 cmH2O with a flow of 8 to 10 L/minute
Category
Treatment - Devices

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
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Ebrahim Esfandiari
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Hezar-Jerib St., Isfahan, Iran
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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

Person responsible for general inquiries

Contact
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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