

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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) $\leq$ 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 $\geq$ 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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Name of organization / entity

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Iran (Islamic Republic of)

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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

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Faculty of Medicine, Isfahan University of Medical Sciences, Hezar-Jerib St., Isfahan, Iran

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ghobad Heidari

Position

Neonatal feloshib

Other areas of specialty/work

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Web page address**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