

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 cmH<sub>2</sub>O (according to infant's birth weight and chest wall expansion), positive end expiratory pressure (PEEP) of 5 to 6 cmH<sub>2</sub>O, rate of 40- 50 breaths/min (according to PaCO<sub>2</sub>), 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 cmH<sub>2</sub>O with a flow of 8 to 10 L/minute. Surfactant [(100 mg/kg per dose will administered if studied neonates, to keep the SPO<sub>2</sub> of > 88% - 92%, need a fraction of inspired oxygen (FIO<sub>2</sub>) of > 30%. INSURE approach, only as rescue therapy, will use in both groups. Infants on NIMV will wean from a PIP of 14-15 cmH<sub>2</sub>O, PEEP 4-5 cmH<sub>2</sub>O, and FIO<sub>2</sub> of < 30%, with acceptable clinical evidence and ABG. Infants on NCPAP will wean from a CPAP of 4 cmH<sub>2</sub>O and FIO<sub>2</sub> 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 SPO<sub>2</sub> 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 PCo<sub>2</sub> > 60, SPO<sub>2</sub> of < 88% with a FIO<sub>2</sub> 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

##### 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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+98 31 1235 5059

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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 cmH<sub>2</sub>O (according to infant's birth weight and chest wall expansion), positive end expiratory pressure (PEEP) of 5 to 6 cmH<sub>2</sub>O, rate of 40- 50 breaths/min (according to PaCO<sub>2</sub>), 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 cmH<sub>2</sub>O 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

##### 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

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

##### Street address

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Neonatologist

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

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**Full name of responsible person**

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Assistant professor of neonatology

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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*