# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparison of two methods of respiratory support: Nasal Continuous positive Airway Pressure (NCPAP) and Nasal Intemitant Positive Pressure Ventilation (NIPPV) after less invasive surfactant administration (LISA) in preterm infants 28 to 36 weeks of age with respiratory distress syndrome, a Randomized clinical trial

## Protocol summary

**Study aim**

Comparison of two methods of respiratory support: NCPAP and NIPPV after less invasive surfactant administration (LISA) in preterm infants with respiratory distress syndrome

**Design**

Sample size will be 96 people in two equal groups of 48 people, randomization using sealing envelope method without replacement, The person evaluating the outcome will not know the type of intervention ( single blind)

**Settings and conduct**

This study will be performed in the neonatal intensive care unit of Fatemieh Hospital in Hamadan. In this study, eligible infants will be randomly assigned to one of the NCPAP or NIPPV. NCPAP Group will apply continuous airway pressure through a mask or nose pendulum with 4 cm of water pressure and 40% fraction of inspired oxygen. When saturation 4 cm water, , FIO2 less than 30% and oxygen saturation 90 to 94% achieved, CPAP will be disconnected and the patient will be under oxygen therapy with oxy hood. NIPPV group will be ventilated with Nasal Intemitant Positive Pressure through the nose. By improving the quality of the baby's oxygen supply, we gradually reduce the PIP by 2 cm to 14 cm. Then the respiratory rate will be reduced by 5 to 10 per minute Until spontaneous breathing increases

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: 28 to 36 weeks gestational age, respiratory distress syndrome, Fractional Inspired Oxygen (Fio2)>40 and need to treatment with surfactant in less than 24 hours after birth. Exclusion Criteria: congenital heart disease, other major congenital anomalies

**Intervention groups**

Intervention group: Under ventilation with continuous positive airway pressure through the nose with maximum pressure control group: Nasal Intemitant Positive Pressure Ventilation through a mask or nose pendulum

**Main outcome variables**

need to respiratory support and ventilation within a week, hospital stay and mortality

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20151123025202N9**
Registration date: **2020-06-19, 1399/03/30**
Registration timing: **retrospective**

Last update: **2020-06-19, 1399/03/30**
Update count: **0**

**Registration date**

2020-06-19, 1399/03/30

**Registrant information**

**Name**

Abbas Moradi

**Name of organization / entity**

Hamedan University of Medical Of Science

**Country**

Iran (Islamic Republic of)

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+98 81 3838 0097

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-01-15, 1398/10/25

**Expected recruitment end date**
2020-04-19, 1399/01/31

**Actual recruitment start date**
2020-01-15, 1398/10/25

**Actual recruitment end date**
2020-04-19, 1399/01/31

**Trial completion date**
2020-05-04, 1399/02/15

**Scientific title**
Comparison of two methods of respiratory support: Nasal Continuous positive Airway Pressure (NCPAP) and Nasal Intemitant Positive Pressure Ventilation (NIPPV) after less invasive surfactant administration (LISA) in preterm infants 28 to 36 weeks of age with respiratory distress syndrome, a Randomized clinical trial

**Public title**
Treatment of respiratory distress syndrome in preterm infants

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
gestational age of 28-37 weeks With distress syndrome Fraction of inspired oxygen>40 Require treatment with surfactant in less than 24 hours after birth

**Exclusion criteria:**
APGAR score<5 Suffering from any congenital disease

**Age**
From **1 day** old to **28 days** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **96**
Actual sample size reached: **98**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
We will provide 96 cards and will write letter I on 48 for intervention and on the other 48 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, randomly select one of the envelopes and open it, based on selected letter ( I or C) patients assign it to the intervention or control group.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The person evaluating the outcome will be unaware of the type of intervention

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Hamadan Univercity of Medical Science

**Street address**
Ṡhahid Fahmideh Vvenue

**City**
Hamadan

**Province**
Hamadan

**Postal code**
6517838697

**Approval date**
2020-01-11, 1398/10/21

**Ethics committee reference number**
IR.UMSHA.REC.1398.866

## Health conditions studied

### 1

**Description of health condition studied**
neonatal respiratory distress syndrome

**ICD-10 code**
P22.0

**ICD-10 code description**
Respiratory distress syndrome of newborn

## Primary outcomes

### 1

**Description**
respiratory support

**Timepoint**
First week of birth

**Method of measurement**
Investigation of FIO2 and analysis of arterial blood gases

## Secondary outcomes

### 1

**Description**
hospitalization duration

**Timepoint**
From hospitalization to discharge

**Method of measurement**

Review of infant medical records

**2**

**Description**
mortality
**Timepoint**
From hospitalization to discharge
**Method of measurement**
Review of infant medical records

## Intervention groups

**1**

**Description**
Intervention group: Nasal Intermittent Positive Pressure Ventilation (NIPPV) after less invasive surfactant administration (LISA). This group intermittently will expose to higher levels of air pressure through the same device attached to the nose. Maximum Respiratory Pressure Group (PIP) receives 18-20 cm H2O, PEEP 5-6 cm H2O, respiratory rate 30-40 per minute, Inhalation time 0.35-0.40 seconds, flow rate 6-8 liters per minute.
**Category**
Treatment - Devices

**2**

**Description**
Control group: Nasal Continuous positive Airway Pressure (NCPAP). This Group will apply continuous airway pressure through a mask or nose pendulum with 4 cm of water pressure and 40% fraction of inspired oxygen. When saturation 4 cm water, , FIO2 less than 30% and oxygen saturation 90 to 94% achieved, CPAP will be disconnected and the patient will be under oxygen therapy with oxy hood. By improving the quality of the baby's oxygen supply, we gradually reduce the PIP by 2 cm to 14 cm. Then the respiratory rate will be reduced by 5 to 10 per minute Until spontaneous breathing increases
**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Fatemieh Hospital
**Full name of responsible person**
Dr Mohammad Kazem Sabzehei
**Street address**
Pasdaran
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6517789971
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
dr Saeid Bashirian
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Shahid Fahmide Ave
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**Email**
vc_research@umsha.ac.ir
**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Hamedan University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Abbas Moradi
**Position**
Coach
**Latest degree**
Master
**Other areas of specialty/work**

Epidemiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
No more information

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available