

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 Intermittent 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 Fatemeh 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 Intermittent 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 Intermittent 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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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 Intermittent 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 University of Medical Science

Street address

Shahid 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

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Pasdaran

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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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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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Position

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Other areas of specialty/work

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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