

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of efficacy and complications of NIPPV vs NCPAP in preterm infants with respiratory distress admitted in NICU

Protocol summary

Summary

Premature infants with respiratory distress syndrome (RDS) may require respiratory support. Because mechanical ventilation (by endotracheal ventilation) is associated with morbidity, the trend today is to minimize the use of mechanical ventilation. Nasal intermittent positive pressure ventilation (NIPPV) and nasal continuous positive airway pressure (NCPAP) are non invasive treatment for RDS. Application of NCPAP and NIPPV are associated with benefits in terms of reduced respiratory failure, reduced complications, and mortality, in neonates with RDS. We aim to determine whether NCPAP and NIPPV would have different survival rate and possible complications. This prospective clinical trial performs on 120 neonates with RDS. All consecutively born preterm infants with gestational age between 28 to 36 weeks, admitting to Afzalipour neonatal intensive care unit, Kerman, Iran, with respiratory distress and silverman-Anderson retraction score of 6 and 7 are included. Babies are excluded if there is significant morbidity except respiratory distress. The randomization is performed applying minimization technique with respect to baby's gender and birth weight and the newborn will put in NCPAP or NIPPV group. The main outcome of this study is lack of response to treatment in regard to survival rates. We will also compare treatment options in terms of duration of oxygen therapy, duration of hospital stay, and hospitalization costs. We will also assess the incidence of neonatal morbidities in 2 treatment groups: pneumothorax, PDA and IVH.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202273250N6**

Registration date: **2012-03-12, 1390/12/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

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Bahareh Bahman Bijari

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of NIPPV vs NCPAP in preterm infants with respiratory distress admitted in NICU

Public title

Comparison of efficacy and complications of Nasal intermittent positive pressure ventilation (NIPPV) and nasal continuous positive airway pressure (NCPAP) in

preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All consecutively born preterm infants with gestational age 28 to 36 weeks, admitted to Afzalipour neonatal intensive care unit with respiratory distress and silverman- Anderson retraction score of 6 and 7. Exclusion criteria: Babies were excluded if there was significant morbidity apart from RDS including cardiac disease, congenital malformation including congenital diaphragmatic hernia, tracheoesophageal fistula and cleft lip/palate, babies with respiratory distress secondary to severe asphyxia (Apgar score <3 at 1 and 5 minute or PH<7/12 or if they had cardiovascular or respiratory instability because of sepsis, anemia or severe intraventricular hemorrhage (IVH) on admission.

Age

To 1 year old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman university of medical sciences

Street address

kerman University of medical science, Jomhoori blvd

City

Kerman

Postal code

Approval date

2012-01-12, 1390/10/22

Ethics committee reference number

K-90/328

Health conditions studied

1

Description of health condition studied

respiratory distress in neonates

ICD-10 code

p22,p22.0,

ICD-10 code description

Respiratory distress syndrome of newborns

Primary outcomes

1

Description

Response to treatment

Timepoint

During hospitalization and using NCPAP and NIPPV

Method of measurement

comparing survival rates

Secondary outcomes

1

Description

Incidence of pneumothorax

Timepoint

During hospitalization and using NCPAP and NIPPV

Method of measurement

Taking chest x rays on admission and deterioration of clinical status

2

Description

Incidence of PDA

Timepoint

During hospitalization and using NCPAP and NIPPV

Method of measurement

Echo cardiography on admission and deterioration of clinical status

3

Description

Incidence of IVH

Timepoint

During hospitalization and using NCPAP and NIPPV

Method of measurement

Cranial ultra sonography on admission and deterioration of clinical status

Intervention groups

1

Description

Intervention: ventilatory NIPPV

Category

Treatment - Devices

2

Description

Intervention: ventilatory NCPAP

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Medical Center

Full name of responsible person

Reza Mahdian Jouybari

Street address

Mostafa Khomeini blvd

City

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Sponsors / Funding sources

1

Sponsor

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Kerman university of medical sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Reza Mahdian Jouybari

Position

Fellowship in neonatology

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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