Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of NCPAP and NIPPV in premature infants with RDS after extubation in NICU ward of Najmiyeh Hospital

Protocol summary

Summary

This study was conducted to compare two NCPAP(nasal continuous positive airway pressure) and NIPPV (nasal intermittent positive pressure ventilation) methods in infants with respiratory distress syndrome (RDS). Patients with gestational ages of less than 34 weeks, birthweight of less than 1800 gr, respiratory distress despite receiving Surfactant and mechanical ventilation were included in the study. Infants with anomalies in nasopharyngeal path, heart or lungs were excluded from the trial. After primary care and extubation infants were randomly allocated to two groups; first group underwent respiratory support by NCPAP using small mask and the second group received NIPPV using nasal prongs. Demographic information as well as required duration of hospitalization, oxygen therapy, respiratory protection, need for re-intubation and complications were recorded in a pre-designed checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050517413N25**
Registration date: **2017-06-12, 1396/03/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-12, 1396/03/22

Registrant information

Name

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Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of NCPAP and NIPPV in premature infants with RDS after extubation in NICU ward of Najmiyeh Hospital

Public title

Comparing the effectiveness of two mask and nasal tube ventilation methods in premature infants with respiratory failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:gestational ages of less than 34 weeks ; birthweight of less than 1800 gr; respiratory distress despite receiving Surfactant and mechanical ventilation; needed FIO2 of less than 60% after extubation Exclusion criteria:anomalies in nasopharyngeal path, heart or lungs; chromosomal anomalies; intraventricular

hemorrhage (IVH); not willing to participate

Age
To **28 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics Committee of Baqiyatallah University of Medical Sciences

Street address
Nosrati ave., South Sheykh Bahaei, Mollasadra st., Vanaq sq., Tehran

City
Tehran

Postal code

Approval date
2016-08-01, 1395/05/11

Ethics committee reference number
IR.BMSU.REC.1395.174

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome of newborn

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Duration of ventilation

Timepoint
After intervention

Method of measurement
Time record by nurse

2

Description
Oxygen Saturation

Timepoint
After intervention

Method of measurement
Pulse Oxymetry

3

Description
Arterial oxygen pressure

Timepoint
After intervention

Method of measurement
Arterial Blood Gas Assessment

4

Description
Respiratory rate

Timepoint
After intervention

Method of measurement
one minute counting by nurse

Secondary outcomes

1

Description
Abdominal Distention

Timepoint
After intervention

Method of measurement
Physical examination

2

Description
Mortality

Timepoint
After intervention

Method of measurement
Recording mortality cases

3

Description
Intraventricular hemorrhage

Timepoint
After intervention

Method of measurement

Brain sonography

4

Description
Necrotizing Enterocolitis
Timepoint
After intervention
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Ventilation by NCPAP
Category
Treatment - Other

2

Description
Control group: Ventilation by NIPPV
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Najmiyeh Hospital
Full name of responsible person
Bita Najafian
Street address
Hafez, Jomhouri st., Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Baqiyatallah University of Medical Sciences
Full name of responsible person
Morteza Izadi
Street address
Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Baqiyatallah 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
Student Research Committee, Baqiyatallah University of Medical Sciences, Tehran, Iran
Full name of responsible person
Mohammad Hossein Khosravi
Position
Secretary-General
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Person responsible for scientific inquiries

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Bita Najafian
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Person responsible for updating data

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Student Research Committee, Baqiyatallah University of medical sciences, Tehran, Iran.

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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