Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Nasal continuous positive airway pressure (NCPAP) versus Humidified high flow nasal cannula (HHFNC) in treatment of premature infants with respiratory distress

Protocol summary

Study aim

Overall Objective: In this study, the-therapeutic effect of Nasal high frequency ventilation(HHFNC) versus nasal continuous positive airway pressure(NCPAP) for treatment of respiratory distress syndrome has been compared

Design

In this randomized control trial study 54 premature infants with respiratory distress syndrome after surfactant therapy were randomly as every other one recruited in to two groups(HHFNC vs NCPAP) and their outcomes were compared.In NCPAP group we used peep=4-6 and flow=8 lit/min and in HHFNC group we used flow=4-7 lit/min

Settings and conduct

In this study premature infants with respiratory distress syndrome whom were admitted to Shohada Hospital and Mahdieh Hospital after surfactant therapy were randomly recruited in to two groups(HHFNC vs NCPAP) and their outcomes were compared.

Participants/Inclusion and exclusion criteria

inclusion criteria premature infants with respiratory distress syndrome(RDS) exclusion criteria - congenital heart diseases - asphyxia - septic shock - multiple anomaly

Intervention groups

HHFNC GROUP :In this group, using an oxygen blender, treatment is given by giving oxygen at a suitable and moist concentration and with a flow of 4 to 7 liters per minute through the nasal cannula. NCPAP GROUP:In this group, the treatment is done by using the CPAP mode from the ventilator device and by adjusting the flow of 8 liter per minute and PEEP 5 to 7 and the appropriate concentration of oxygen through the nasal cannula.

Main outcome variables

the length of hospital stay the length of oxygen delivery nasal trauma bronchopulmonary displasia death

General information

Reason for update

Acronym

Nasal continuous positive pressure(NCPAP)

IRCT registration information

IRCT registration number: **IRCT20151122025184N2**
Registration date: **2021-07-29, 1400/05/07**
Registration timing: **retrospective**

Last update: **2021-07-29, 1400/05/07**
Update count: **0**

Registration date

2021-07-29, 1400/05/07

Registrant information

Name
Roya Taheri Tafti
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Nasal continuous positive airway pressure (NCPAP) versus Humidified high flow nasal cannula (HHFNC) in treatment of premature infants with respiratory distress

Public title
:NCPAP versus HHFNC in treatment of premature infants with respiratory distress
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
premature infants with GA fewer than 37 weeks
premature infants with respiratory distress syndrome
premature infants with respiratory distress syndrome who can extubate after surfactant therapy
Exclusion criteria:
congenital heart diseases asphyxia septic shock multiple anomaly
Age
To **3 days** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
permuted block randomization by tossing coin
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
Organizational Committee of Ethics in Biomedical Research, Vice Chancellor for Research, Shahid Behe
Street address
tajrish square
City
tehran
Province
Tehran
Postal code
1989934148
Approval date
2019-06-23, 1398/04/02
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.135

Health conditions studied

1

Description of health condition studied
respiratory distress syndrome in premature infants
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
the extubation failure rate in two groups of NCPAP and HHFNC within 7 days after the intervention
Timepoint
within 7 days after INSURE(intubation and surfactant injection and extubation)
Method of measurement
EXAMINATION AND STUDY OF FILES

2

Description
the length of oxygen requirement after surfactant therapy
Timepoint
during after surfactant therapy
Method of measurement
EXAMINATION AND STUDY OF FILES

Secondary outcomes

1

Description
Pneumotorax and air leaks of the plural space due to the two type of noninvasive ventilation during the period of receiving respiratory support
Timepoint
During the period of receiving noninvasive respiratory support (intervention)
Method of measurement
EXAMINATION AND CXR AND STUDY OF FILES

2

Description
Intraventricular brain hemorrhage during the period of receiving respiratory support
Timepoint

During the period of receiving noninvasive respiratory support (the intervention)

Method of measurement

examination and brain sonography

3

Description

hospital length of stay

Timepoint

The total length of hospitalization of the studied neonates

Method of measurement

study of files

4

Description

nasal trauma includes ulceration and necrosis during the period of receiving respiratory support

Timepoint

During the period of receiving respiratory support(the intervention)

Method of measurement

inspection

Intervention groups

1

Description

Intervention group: HHFNC GROUP:In this group, using an oxygen blender, treatment is given by giving oxygen at a suitable and moist concentration and with a flow of 4 to 7 liters per minute through the nasal cannula.

Category

Treatment - Devices

2

Description

Intervention group: NCPAP GROUP:In this group, the treatment is done by using the CPAP mode from the ventilator device and by adjusting the flow of 8 liter per minute and PEEP 5 to 7 and the appropriate concentration of oxygen through the nasal cannula.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh hospital

Full name of responsible person

dr roya taheritafti

Street address

shoosh street

City

tehran

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Tehran

Postal code

1185817311

Phone

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Email

mahdiyeh_hospital@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

shohada e tajrish hospital

Full name of responsible person

dr roya taheritafti

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Province

Tehran

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Clinical Research Development Unit of ShohadaTajrish Hospital

Street address

tajrish square

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tehran

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pr_shohada@sbmu.ac.ir

Web page address

http://shmc.sbmu.ac.ir/index.jsp?pageid=6173&p=1

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
dr roya taheritafti
Position
ASISTANT PROFESSOR
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available