

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 Mahdiah 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 dysplasia 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

Country

Iran (Islamic Republic of)

Phone

+98 21 8828 8037

Email address

royataheritafti@sbmu.ac.ir

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
Mahdiah hospital
Full name of responsible person
dr roya taheritafti
Street address
shoosh street
City
tehran

Province
Tehran
Postal code
1185817311
Phone
+98 21 5506 2628
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
Street address
tajrish square
City
tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8000
Email
Pr_shohada@sbmu.ac.ir

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
City
tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8000
Email
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

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

KOOYE NASR STREET

City

TEHRAN

Province

Tehran

Postal code

1446943853

Phone

+98 21 8828 8037

Email

royataheritafti@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr roya taheritafti

Position

asistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

kooye nasr

City

tehran

Province

Tehran

Postal code

1446943853

Phone

+98 21 8828 8037

Email

royataheritafti@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr roya taheritafti

Position

asistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

kooye nasr

City

tehran

Province

Tehran

Postal code

1446943853

Phone

+98 21 8828 8037

Email

royataheritafti@yahoo.com

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