Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing High flow nasal cannula versus nasal CPAP for INSURE treatment of neonatal respiratory distress syndrome

Protocol summary

Summary

In this study we will compare NCPAP (Nasal Continuous Positive Airway Pressure) with HFNC (High Flow Nasal Cannula) in newborn infants with respiratory distress syndrome (RDS) who will place on one of this method after receiving surfactant and extubation. This will be a prospective Balanced Block Randomization study among 54, 28-34 weeks, newborns with respiratory distress syndrome who are admitted to the NICUs' at Arash Hospital and Children's Medical Center. Patients will be excluded with major congenital anomalies, congenital heart diseases, and Apgar score less than 5 in 5 minutes. To avoid misdistribution of gestational age and sex, the patients will systematically be blocked on gestational age and sex using four categories; 28-30 wk males, 28-30wk females, 31-34wk males, 31-34wk females. After ethical approval and explanation for parents and obtaining written informed consent, neonates with indication of exogenous surfactant administration will be intubated, surfactant will be administrated and then they will be extubated within a few hours by physician judgment. After extubation one group of patients will receive NCPAP, and another group will receive HFNC. These patients will be followed closely and monitored for hypercarbia (Pco2≥60) with a pH of <7.25, hypoxemia Pao2<50 with FIO2>0.7, for reintubation. The primary outcome is remaining extubatation for at least 3 days and secondary outcomes is duration of oxygen therapy and hospitalization, and survival. Two groups will finally be compared with each other by student's t-test for continuous data and x2 test and fisher's exact test for categorical data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201228800N1**

Registration date: **2012-08-11, 1391/05/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-11, 1391/05/21

Registrant information

Name

Maliheh Kadivar

Name of organization / entity

Children's Medical Center, Terhan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 7648

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Recruitment status

Recruitment complete

Funding source

Maternal, Fetal & Neonatal Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing High flow nasal cannula versus nasal CPAP for INSURE treatment of neonatal respiratory distress syndrome

Public title
Comparing two types of noninvasive mechanical ventilation in neonatal respiratory distress after surfactant replacement therapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: preterm infants with respiratory distress; need for surfactant therapy; gestational age 28-34 wks; parental written consent. Exclusion criteria: babies with major congenital anomalies; congenital heart disease; asphyxia with apgar score less than 5 in 5 minutes.
Age
To **28 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
history of corticosteroid prophylaxis in perinatal period and GA assessment

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committe of Tehran University of Medical Sciences
Street address
#16 Azar St, Ethics Research Center
City
Tehran
Postal code
Approval date
2012-07-10, 1391/04/20
Ethics committee reference number
16342

Health conditions studied

1

Description of health condition studied
INSURE in Neonatal Respiratory Distress Syndrome
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Reintubation
Timepoint
after intervention till 3 days
Method of measurement
ABG assessment and RDS score and FIO2 requirment

Secondary outcomes

1

Description
duration of oxygen therapy
Timepoint
after intervention till discharge
Method of measurement
day

2

Description
amount of oxygen therapy
Timepoint
after intervention
Method of measurement
fraction of oxygen

3

Description
survival
Timepoint
after intervention till discharge
Method of measurement
alive or death

Intervention groups

1

Description
control group: intubation, surfactant replacemnt therapy, extubation to NCPAP
Category
Other

2

Description

Case group: intubation, surfactant replacemnt therapy, extubation to HFNC

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Subspeciality Center

Full name of responsible person

Shahin Nariman- Maliheh Kadivar

Street address

#162 Martyr Abdlohamid Alley, Baghdarnia St, Resalat Ave

City

Tehran

2

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Maliheh Kadivar- Razieh Sangsari

Street address

No. 62, Gharib St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Maternal, Fetal & Neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Nayeri MD

Street address

Valiasar Hospital, Imam Khomeini Complex Center, Keshavarz Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Maternal, Fetal & Neonatal Research Center, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahin Nariman MD

Position

Neonatologist, Chief of Neonatal Intensive Care Unit of Arash Hospital

Other areas of specialty/work

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Position

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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