

# 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

Registration timing: **registered\_while\_recruiting**

#### 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 ( $P_{co2} \geq 60$ ) with a pH of  $< 7.25$ , hypoxemia  $P_{ao2} < 50$  with  $FIO_2 > 0.7$ , for reintubation. The primary outcome is remaining extubation 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  $\chi^2$  test and fisher's exact test for categorical data.

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

##### Email address

kadivarm@tums.ac.ir

#### 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

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201228800N1**

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

##### 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 Committee 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 requirement

## 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 replacement therapy, extubation to NCPAP

#### Category

Other

### 2

#### Description

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

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Arash Subspecialty Center

**Full name of responsible person**

Shahin Nariman- Maliheh Kadivar

**Street address**

#162 Martyr Abdlohamid Alley, Baghdarnia St, Resalat Ave

**City**

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**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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Children's Medical Center, Tehran University of Medical Sciences

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**Position**

Neonatologist; Chief of Neonatal Intensive Care Unit of Children's Medical Center

**Other areas of specialty/work**

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**Position**

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**Other areas of specialty/work**

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**Web page address**

## 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*