# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Investigate various strategies for weaning nasal continuous positive airway pressure (NCPAP) in premature neonates with respiratory distress syndrome

## Protocol summary

**Study aim**

Comparison of different strategies for stopping positive airway pressure (NCPAP) in premature infants with respiratory distress syndrome.

**Design**

Clinical trial without control group, community-based and pragmatic, with parallel groups, no blinding, randomized

**Settings and conduct**

In this study, clinical trials of premature infants 26 to 32 weeks and six days of age with respiratory distress syndrome were born at the Al-Zahra Educational and Medical Center in Tabriz with respiratory scordiosis (ACORN) 5 to 8%.

**Participants/Inclusion and exclusion criteria**

Exclusion Criteria 1. Infants with chromosomal defects 2. Infants with severe congenital anomalies or severe congenital heart disease 3. Infants with sphincter with Apgar in the fifth minute less than 7 4. Infants under mechanical ventilation 5. Revived (advanced) babies 6. Babies with parental dissatisfaction with entering the study

**Intervention groups**

The first group underwent positive airway pressure to 5% and oxygen depletion consumption to 30% under respiratory support with HFNC 3_5 liters per minute and oxygen depletion of 30%. The second group gradually reduced their airway stability (PEEP) by 1 cm every 8 hours, with positive airway pressure reaching 3% and oxygen depletion reaching 25% The third group, every 8 hours, 1 cm of airway pressure was reduced (PEEP) and with positive pressure, airway was reduced to 3 and oxygen consumption was reduced to 25% in neonatal respiratory support with oxyhoud 5-6 liters per minute and oxygen depletion. Consumption is 30%.

**Main outcome variables**

Respiratory distress rate and apnea Requires oxygen consumption Duration of hospitalization The incidence of chronic lung disease Narcissistic retinopathy Intraventricular hemorrhage The incidence of sepsis

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160102025811N5**
Registration date: **2021-04-05, 1400/01/16**
Registration timing: **retrospective**

Last update: **2021-04-05, 1400/01/16**
Update count: **0**

**Registration date**

2021-04-05, 1400/01/16

**Registrant information**

**Name**

Mirhadi Mousavi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 3327 2094

**Email address**

drmussavihadi@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-03-21, 1398/01/01

**Expected recruitment end date**

2020-03-20, 1399/01/01

**Actual recruitment start date**

2020-03-20, 1399/01/01

**Actual recruitment end date**

2020-03-20, 1399/01/01

**Trial completion date**

2020-03-20, 1399/01/01

**Scientific title**

Investigate various strategies for weaning nasal continuous positive airway pressure (NCPAP) in premature neonates with respiratory distress syndrome

**Public title**

weaning nasal continuous positive airway pressure (NCPAP) in premature neonates with respiratory distress syndrome

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Premature infants 26 to 32 weeks and six days with respiratory distress syndrome (premature onset of respiratory distress in the first 4 hours of life or radiographic findings in favor of respiratory distress syndrome) Positive airway pressure has been implicated in neonatal intensive care unit (NICU).

**Exclusion criteria:**

Infants with chromosomal defects Infants with severe congenital anomalies or severe congenital heart disease Infants with sphincter with Apgar less than 7 minutes Infants under mechanical ventilation Revived (advanced) babies Babies with parental dissatisfaction with entering the study

**Age**

From **104 days** old to **224 days** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

Actual sample size reached: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, clinical trials of premature infants 26 to 32 weeks and six days of age with respiratory distress syndrome were born at the Al-Zahra Educational and Medical Center in Tabriz with respiratory shockorder (ACORN) 5 to 8%. They were airborne (NCPAP) (after the acute phase of the primary disease and the start of weaning with the approval of neonatal subspecialty or neonatal subspecialty assistant), the study entered and the infants were randomly divided into 3 groups by computer guidance.

**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 Tabriz University of Medical Sciences

**Street address**

Av.Azadi, Av.Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

65423987456

**Approval date**

2019-03-27, 1398/01/07

**Ethics committee reference number**

ir.tbzmed.rec.1398.176

## Health conditions studied

### 1

**Description of health condition studied**

Respiratory distress syndrome

**ICD-10 code**

P22.0

**ICD-10 code description**

Respiratory distress syndrome of newborn

## Primary outcomes

### 1

**Description**

respiratory distress syndrome score

**Timepoint**

Prior to intervention in all study groups and daily at specified times until discontinuation of respiratory support

**Method of measurement**

Score based on the number of breaths, need for oxygen, retraction, moaning, breathing sounds , immaturity

### 2

**Description**

Apnea

**Timepoint**

Before the intervention and at certain times daily after the intervention until the cessation of respiratory support

**Method of measurement**

Number of respiratory arrests per hour

### 3

**Description**
Duration of hospitalization
**Timepoint**
From the beginning to the end of the patient's hospitalization
**Method of measurement**
Number of days spent in the hospital

### 4

**Description**
Need to oxygen therapy
**Timepoint**
Before intervention and daily at specified times until discontinuation of respiratory support
**Method of measurement**
10% increase in fraction of inspired oxygen(yes/no)

### 5

**Description**
Retinopathy of Prematurity
**Timepoint**
At 28 days of birth
**Method of measurement**
Ophthalmological consultation

### 6

**Description**
Intraventricular haemorhage
**Timepoint**
At the end of intervention
**Method of measurement**
Brain sonography

### 7

**Description**
Respiratory Distress Syndrome
**Timepoint**
at the end of intervention
**Method of measurement**
Need oxygen after discharge

### 8

**Description**
Mortallity
**Timepoint**
At the end of intervention
**Method of measurement**
Neonate death

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Premature infants 26 to 32 weeks with respiratory distress syndrome, with a positive airway end pressure of 5 and an fraction of inspired oxygen of 30%, Infants underwent respiratory support with a high flow nasal cannula at a rate of 3 liters per minute and an fraction of inspired oxygen of 30%.
**Category**
Treatment - Devices

### 2

**Description**
Premature infants 26 to 32 weeks with respiratory distress syndrome, with a positive airway end pressure of 3 and an fraction of inspired oxygen of 25%, Infants underwent respiratory support with a high flow nasal cannula at a rate of 3 liters per minute and an fraction of inspired oxygen of 25%.
**Category**
Treatment - Devices

### 3

**Description**
Premature infants 26 to 32 weeks with Respiratory Distress Syndrome who gradually decreased 1 cm/H2O of positive airway pressure (PEEP) every 8 hours and when reached 3 cm/H2O positive airway pressure and fraction of inspired oxygen 25% ,infants will be located in oxygen hood with 5-6 liters per minute and fraction of inspired oxygen 30%.
**Category**
Treatment - Devices

### 4

**Description**
Premature infants 26 to 32 weeks with Respiratory Distress Syndrome who gradually decreased 1 cm/H2O of positive airway pressure (PEEP) every 8 hours and when reached 3 cm/H2O positive airway pressure and fraction of inspired oxygen 25% , ventilation support will be cessated and infants will be located in room air.
**Category**
Treatment - Devices

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Alzahra Hospital
**Full name of responsible person**
Mirhadi Mousavi
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Sheshgelan street
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Dr.Rashidi

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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Tabriz University of Medical Sciences

**Proportion provided by this source**
100

**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**
Tabriz University of Medical Sciences

**Full name of responsible person**
Mirhadi Mousavi

**Position**
Assistant Professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Pediatrics

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## Person responsible for scientific inquiries

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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**
Not applicable