

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

drmussaviahadi@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 haemorrhage

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

Mortality

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 ceased 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

Street address

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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Av.Azadi , Av.Golgasht
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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
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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