Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of assisted ventilation using nasal continuous positive air way pressure versus nasal duo positive air way pressure on the clinical course of neonates with gestational age between 28-34 week with respiratory distress syndrome :A randomized controlled trial.

Protocol summary

Study aim

Determine the effect of assisted ventilation nasal continuous positive air way pressure versus nasal duo positive air way pressure on the clinical course of neonates with gestational age between 28-34 weeks with respiratory distress syndrome

Design

Randomized clinical trial study with parallel groups and blinded ,with sample size of 148 patients

Settings and conduct

this study is conducted in neonatal intensive care unit of Ahwaz Imam Hospital .blindness is done on the patient ,the investigator and the data analyst and only the therapist is the administrative.

Participants/Inclusion and exclusion criteria

Neonates with gestational age of 28-34 weeks with respiratory distress syndrome(RDS) with RDS score between 6-8 according Silverman-Andersen score ,entrance in study, in the first 6 hours of birth.neonate with meconium aspiration ,diaphragmatic hernia ,major congenital anomaly, air way anomaly,severe cardio-vascular instability,asphyxia,metabolic disorder,parental dissatisfaction,birth outside the hospital studied,start of invasive mechanical ventilation from the beginning of admission,cyanotic heart disease ,and gestational age less than 28 weeks or more than 34 weeks are not included in this study.

Intervention groups

In this study, neonates are randomly divided into two group of neonate under nasal continuous positive air way pressure and neonates under nasal duo positive air way pressure

Main outcome variables

The primary outcome included failure of non invasive ventilation that requiring tracheal intubation and mechanical ventilation during 72 hours after entrance to study.secondary outcome included ,intra ventricular hemorrhage ,chronic lung disease ,patent ductus arteriosus ,air leak syndromes ,occurrence apnea,death ,frequency of use of surfactant and duration of admission in two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180821040847N1**
Registration date: **2018-09-10, 1397/06/19**
Registration timing: **prospective**

Last update: **2019-05-04, 1398/02/14**
Update count: **1**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

Mina Agahin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of assisted ventilation using nasal continuous positive air way pressure versus nasal duo positive air way pressure on the clinical course of neonates with gestational age between 28-34 week with respiratory distress syndrome :A randomized controlled trial.

Public title
."Effect of nasal continuous positive air way pressure on the clinical course of neonates with respiratory distress syndrome" ."Effect of nasal duo positive air way pressure on the clinical course of neonates with respiratory distress syndrome"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm neonate with gestational age of 28-34 weeks With respiratory distress syndrome With respiratory distress syndrome score of 6-8 according to Silver man-Andersen score Entrance to study in primary 6 hours of birth
Exclusion criteria:
Major congenital abnormalities Air way abnormalities Sever cardio-vascular instability Sever asphyxia(Apgar score<=3 at minute 1 and minute 5 of birth or potential hydrogen(PH) <=7/1) Dissatisfaction of parents Meconium aspiration Diaphragmatic hernia Initioation of invasive mechanical ventilation from beginning of hospitalization Gestational age <28 week or >34 week Metabolic disorder Respiratory difficulties caused by nervous system disease or muscle disease cyanotic heart disease Birth at out of hospital studied
Age
From **1 day** old to **1 day** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **148**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study ,individuals are randomly divided into two groups of nasal continuous positive air way pressure and duo positive air way pressure based on random quadratic randomization method which is cited by the http://www.sealedenvelope.com/simple-randomiser/v1/lists site.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study patient who are actually neonate,after obtaining consent from the parents ,randomly enter the study .And the implementation of the study is the responsibility of the therapist ,and the neonate does not interfere with the setting of the device.Also Researcher and data analyst do not interfere with the implementation of the study .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences,Esfand avenue,Golestan Bulvar
City
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Province
Khouzestan
Postal code
61357-15794
Approval date
2018-08-04, 1397/05/13
Ethics committee reference number
IR.AJUMS.REC.1397.365

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrom
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Non invasive ventilation failure that require intubation and mechanical ventilation during 72 hours after

entrance to study

Timepoint

During the first 72 hours of admission to study

Method of measurement

The failure of treatment is considered to be when there are one or two of the following conditions.first condition included partial pressure of carbon dioxide in arterial blood >60 millimeter of mercury and potential hydrogen of arterial blood<7/2 and partial pressure of oxygen in arterial blood <50 millimeter of mercury with fraction of inspired oxygen >60% and positive end expiratory pressure >8 centimeters of water in method of nasal continuous positive air way pressure and duo pressure >15 centimeters of water and positive end expiratory pressure >8 centimeters of water and fraction of oxygen of >60% in method of nasal duo positive air way pressure .second condition included worsening of clinical conditions (increased respiratory distress by tachypnea and severe retraction of chest)or prolong apnea (apnea for more than 20 seconds)or repeated apnea for more than 2 time in 24 hours with cyanosis and bradycardi <100 beat in minute that require ventilation with bag and mask.

Secondary outcomes

1

Description

Intra ventricular hemorrhage

Timepoint

brain ultrasound performed by the radiologist on days 1 and 3 and 7 and 14 and 28 after admission

Method of measurement

By ultrasound of the brain performed by the radiologist

2

Description

Patent ductus arteriosus (A duct that establishes the connection between the pulmonary artery and the aorta that after birth,it is naturally closed and failure in this will result in patent ductus arteriosus).

Timepoint

During the first 48 hours of birth or presence of clinical symptoms of patent ductus arteriosus like hearing asystolic murmur or hypotension

Method of measurement

Echocardiography is done by the pediatric cardiologist

3

Description

Chronic lung disease(oxygen dependence at gestational age 36 weeks)

Timepoint

Up to 36 weeks gestational age

Method of measurement

Assessment of oxygen dependence by pulse oximetry

4

Description

Air leak syndroms (alveolar rupture due to severe dilation and air entrances to the pleural space)

Timepoint

The length of time the patient is treated with one of two methods of nasal continuous positive air way pressure or nasal Duo positive air way pressure .

Method of measurement

chest x ray

5

Description

Duration of hospitalization

Timepoint

From hospitalization until discharge

Method of measurement

Based on patient records

6

Description

The occurrence of death

Timepoint

During treatment with either of the two methods studied

Method of measurement

Clinical evaluation of the absence of vital signs

7

Description

Apnea (Respiratory interruption that last more than 20 seconds or less than 20 seconds but with cyanosis and bradycardia less than 100 beats per minute).

Timepoint

During treatment with either of the two methods studied

Method of measurement

Pulse oximetry

8

Description

The number of surfactants used(A type of lipoprotein that is present in the inner wall of the alveolus .this drug used for respiratory distress syndrome) .

Timepoint

First 48 hours after intervention

Method of measurement

Pulse oximetry and need to oxygen fraction>40% and positive end expiratory pressure >= 4-6 and measurement of arterial blood gases

Intervention groups

1

Description

Intervention group:The first group is neonates who are under nasal continuous positive air way pressure. fabian device from switzerland country , is used to apply this method.

Category
Treatment - Devices

2

Description
Intervention group: In second group ,neonate are under nasal duo positive air way pressure .Fabian device from switzerland country,is used to apply this method.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Neonatal Intensive Care Unit of Ahvaz Imam Khomeini Hospital
Full name of responsible person
Mina Agahin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mina Agahin
Position
Fellowship in neonatal medicine
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering that this study will be carried out for the first time in Iran,and only at the Imam Khomeini Hospital of Ahwaz and not multi center ,we do not decide to publish individual participants data ,but the results are certainly presented as an article.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available