Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of effectiveness and ineffectiveness of the nasal cannula with high pressure and continuous positive airway pressure through the nose for the treatment of premature infants with respiratory distress syndrome

Protocol summary

Summary

This study will done with aim to investigate the effectiveness of the nasal cannula with high pressure and continuous positive airway pressure through the nose for the treatment of premature infants with respiratory distress syndrome. This study is not-blinded clinical trial. The study population will included all premature infants with less than 37 weeks gestational age with respiratory distress syndrome, hospitalized in Imam Reza Hospital in Kermanshah city that require surfactant injection in Insure way, that the number of 200 subjects are selected and randomly are assigned to experimental and control groups. In the first group after the injection of the surfactant and Extube, Placed under respiratory support with nasal (CPAP) and in the second group respiratory support is established using the oxygen hot and humid high flow through nasal cannula (HFNC). In the first group initiation of treatment is with 4 ml of water and Fio2 40% and in the second group Blender and nasal cannula devices with an inner diameter of 2 mm is used for administering oxygen . Then in both groups, the duration of treatment with nasal or nasal cannula, need for mechanical ventilation, need to prescribe another dose of surfactant, damage to the nasal septum, intracerebral bleeding, compared with each other during and end of the study. Inclusion criteria: premature infants under 37 weeks and over 24 weeks; respiratory distress syndrome; written informed consent of the parents Exclusion criteria: Apgar score of fifth minute less than 5; there are syndromes or major congenital anomalies; congenital heart disease, mother Radiography and chorioamnionitis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100814333N41**
Registration date: **2015-10-19, 1394/07/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-19, 1394/07/27

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1821 4653
Email address
fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-07-06, 1394/04/15

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative study of effectiveness and ineffectiveness of the nasal cannula with high pressure and continuous positive airway pressure through the nose for the treatment of premature infants with respiratory distress syndrome

Public title
Comparison of the effects of High flow nasal cannula versus nasal continuous positive Air way pressure in treatment of respiratory distress syndrome in premature newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: premature infants under 37 weeks and over 24 weeks; respiratory distress syndrome; written informed consent of the parents Exclusion criteria: Apgar score of fifth minute less than 5; there are syndromes or major congenital anomalies; congenital heart disease, mother Radiography and chorioamnionitis
Age
From **6 months** old to **9 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Random method according to the random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2015-08-18, 1394/05/27
Ethics committee reference number
kums.rec.1394.90

Health conditions studied

1

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

Primary outcomes

1

Description
Cerebral hemorrhage
Timepoint
During study
Method of measurement
By cerebral ultrasound

2

Description
Necrotizing enterocolitis
Timepoint
During study
Method of measurement
Based on the clinical symptoms and a doctor observation and an abdominal radiograph

3

Description
Amount of nasal septum injury
Timepoint
During study
Method of measurement
Based on the doctor examination

4

Description
Air leak syndrome
Timepoint
During study
Method of measurement
Based on the clinical symptoms and doctor observation and chest radiography

5

Description
Broncho-pulmonary dysplasia
Timepoint

During study

Method of measurement

Based on the clinical symptoms, doctor observation, x-ray and laboratory

6

Description

The need for re-intubating

Timepoint

During study

Method of measurement

Based on laboratory and doctor clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

In the first group after the injection of the surfactant and Extube, Placed under respiratory support with nasal (CPAP) and initiation of treatment is with 4 ml of water and Fio2 40%. Then the duration of treatment with nasal or nasal cannula, need for mechanical ventilation, need to prescribe another dose of surfactant, damage to the nasal septum, intracerebral bleeding, during and end of the study is investigated

Category

Treatment - Drugs

2

Description

In the second group respiratory support is established using the oxygen hot and humid high flow through nasal cannula (HFNC). Blender and nasal cannula devices with an inner diameter of 2 mm is used for administering oxygen. Then the duration of treatment with nasal or nasal cannula, need for mechanical ventilation, need to prescribe another dose of surfactant, damage to the nasal septum, intracerebral bleeding, during and end of the study is investigated

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Mansour Ahoon

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Homa Babaei

Position

Infants Specialist

Other areas of specialty/work

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Postal code

Phone

+98 83 3427 6300

Fax

Email

HOMA_BABAEI@KUMS.AC.IR

Web page address

Person responsible for updating data

Contact

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