

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparing outcome of surfactant administration via tracheal catheterization during spontaneous breathing (tec-care) with tracheal intubation accompany with positive pressure ventilation (INSURE) in premature neonates with respiratory distress syndrome.

Protocol summary

Summary

This study was designed to compare outcomes of two different procedure of surfactant administration in premature neonates with respiratory distress syndrome. The conventional method of surfactant administration (INSURE) is accompanied by tracheal intubation and positive pressure ventilation, but in the new method surfactant is delivered via a thin endotracheal catheter (TEC - Care), without termination Nasal CPAP. In this method surfactant is injected during delivery of Nasal CPAP with pressure of 8 to 10 cmh₂o. This multi center study is going to be conducted concomitant within NICU of four university hospitals. Alzahra and 29 Bahman Hospital in Tabriz, Shahidbeheshti Hospital in Esfahan and Ommolbanin Hospital in Masshad during 6 months. At least 90 neonate are studied in each group. Including major eligibility objectives: newborns between 27 to 36 week gestational ages; show clinical and radiographical evidences of RDS; need care by Nasal CPAP and surfactant administration. Exclusion criteria are: Infants who have congenital abnormalities; Apgar score less than 6 in min 5. Our main aim of study is to compare incidence of bronchopulmonary dysplasia between two groups. Other indicators that this study will measure for comparison between two groups are: Average hospitalization, Average duration of oxygen, Mechanical ventilation requirement, Incidence of intracranial hemorrhage, Frequency of pneumothorax, Next dose surfactant requirement and incidence of neonatal mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112078314N1**

Registration date: **2013-01-14, 1391/10/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-14, 1391/10/25

Registrant information

Name

Mohammad Heidarzadeh

Name of organization / entity

Health Ministry

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Tabriz University of Medical science

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing outcome of surfactant administration via tracheal catheterization during spontaneous breathing (tec-care) with tracheal intubation accompany with positive pressure ventilation (INSURE) in premature neonates with respiratory distress syndrome.

Public title

Comparing surfactant administration without intubation with conventional method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Neonates with gestational age of 27-36 weeks with respiratory distress syndrome that required surfactant administration; Delivered in Multi center hospitals of (Alzahra and 29 bahman from Tabriz; Ommolbanin from Mashhad and Shahid Beheshti from Esfehan); Were resuscitated according to resuscitation guide line 2006 .Exclusion criteria: Neonates with congenital disease ;Apgar score of less than 6 within 5 minutes .

Age

From **27 years** old to **36 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

No

Secondary trial Id

No

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Medical Faculty, Tabriz University of Medical Sciences, Golgasht street, Tabriz, East Azarbaijan, Iran

City

Tabriz

Postal code

Approval date

2012-04-16, 1391/01/28

Ethics committee reference number

91164

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

Continuous positive airway pressure failure

Timepoint

Half-Hour after intervention

Method of measurement

Increasing respiratory distress syndrome score

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Time of discharge from hospital

Method of measurement

Extracted from the file

2

Description

Intraventricular hemorrhage

Timepoint

7th day after birth

Method of measurement

Cranial ultrasonography by a radiologist

3

Description

Chronic lung disease

Timepoint

36th week of gestational age

Method of measurement

Observation of hospital file for oxygen requirement at 36th weeks of postconceptional age

Azərbaycan, İran
City
Tabriz

Intervention groups

1

Description

Clinical guideline for administering surfactant via TEC-CARE: 1. NCPAP pressure should be increased as much as 8 to 10 cmH₂O 2. In order to decrease secretions of the neonate we administer atropin 5µg/kg before intubation 3. The neonate is intubated by a 5f feeding tube. The tip of the catheter is guided through 1 to 2 cm below the vocal cords. 4. After placement the Feeding tube laryngoscope is removed from the mouth and surfactant is administered slowly. Surfactant is injected slowly over 1 to 3 minutes. 5. If you require Fio₂ over 40% readministration of Surfactants is possible. a. During administration, the baby may be suffering from obstructive apnea then slowly stimulates the baby and increase the percentage of oxygen b. Surfactant reflux into the infant's mouth will normal, it is recommended that if there is no acute respiratory failure suction secretions from baby's mouth should be avoided. c. If severe respiratory failure occurs and there is no response to stimulation and increased spo₂ then ventilate the neonate with nasal prong or nasal mask or bag and mask and after recovery administer surfactant d. After Surfactant administration return NCPAP pressure to 6cmH₂O

Category

Treatment - Devices

2

Description

Clinical Guide line for administering surfactant via INSURE: 1. Neonates are removed from NCPAP. 2. Before intubation 2µg / kg Fentanyl was injected for Sedation 3. Neonate is intubated with endotracheal tube appropriate to weight and gestational age then ensure for its proper place. 4. surfactant is administered by a 5f feeding tube 5. After intubation the neonate is ventilated for 1 min via bag and mask or T-Piece or ventilator until spo₂ is more than 85% 6. Naloxone is administered 0.1 mg / kg. 7. Baby is Extubated 8. NCPAP is once again placed. 9. Assisted ventilation continues by NCPAP

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzara hospital

Full name of responsible person

Dr. Kayvan Mirnia

Street address

Alzara hospital, Artesh street, Tabriz, East

2

Recruitment center

Name of recruitment center

Ommolbanin hospital

Full name of responsible person

Dr. Mohammad Heidarzadeh

Street address

Ommolbanin hospital, Ayatollah Behjat street, Mashhad, Khorasan Razavi, Iran

City

Mashhad

3

Recruitment center

Name of recruitment center

Shahid beshti hospital

Full name of responsible person

Dr. Alirza Sadeghnia

Street address

Shahid beshti hospital, Motahari street, Esfahan, Esfahan, Iran

City

Esfahan

4

Recruitment center

Name of recruitment center

29 Bahman hospital

Full name of responsible person

Dr. Kayvan Mirnia

Street address

29 Bahman hospital, Bolvar 29 bahman, Tabriz, East Azarbaijan, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Children Health Research Center

Full name of responsible person

Dr. Mohammad Reza Barzegar

Street address

Tabriz Children Hospital, Sheshgelan street, Tabriz, East Azarbaijan, Iran

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Children Health Research Center
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

Alzahra hospital

Full name of responsible person

Dr.Kayvan Mirnia

Position

Pediatrician, Fellow ship of neonatology

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Person responsible for scientific inquiries

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Name of organization / entity

Neonatal health office

Full name of responsible person

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Position

Neonatologist, Assistant professor

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Person responsible for updating data

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Name of organization / entity

Neonatal health office

Full name of responsible person

Dr. Mohammad Heidarzadeh

Position

Neonatologist, Director of neonatal health office

Other areas of specialty/work**Street address**

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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