

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of two methods of endotracheal tube and thin catheter for surfactant therapy in neonates with respiratory distress syndrome in NICU

Protocol summary

Study aim

Comparison of two methods of endotracheal tube and thin catheter for surfactant therapy in neonates with respiratory distress syndrome in neonatal intensive care unit

Design

A randomized clinical trial with parallel two intervention groups (1 and 2), single blinded, randomized, N= 80 neonates

Settings and conduct

This research includes preterm neonates, admitted to hospitals affiliated to Shiraz University of Medical Sciences who need receiving surfactant. Blinding in this research is single blind and statistical analyzer does not know neonate is in which group

Participants/Inclusion and exclusion criteria

inclusion criteria: Infants born with a gestational age of 25 to 37 weeks Admitted to the neonatal intensive care unit (NICU) exclusion criteria:Respiratory distress due to cardiac causes, hemodynamic instability, sepsis and any cause other than surfactant deficiency

Intervention groups

In this study, the first group will receive surfactant by Intubation-Surfactant-Extubation (INSURE) and Endotracheal tube (ETT) method and the second group will receive surfactant by minimally invasive surfactant therapy (MIST) technique

Main outcome variables

Duration of need for mechanical ventilation; Duration of Nasal continuous positive airway pressure (NCPAP) requirement; amount of FiO₂ required after receiving the surfactant; Bronchopulmonary Dysplasia (BPD) prevalence; Need to prescribe a second dose of surfactant

General information

Reason for update

Acronym

RDS: respiratory distress syndrome

IRCT registration information

IRCT registration number: **IRCT20211006052685N2**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **retrospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

mehrdad rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3612 2218

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	
Comparison of two methods of endotracheal tube and thin catheter for surfactant therapy in neonates with respiratory distress syndrome in NICU	
Public title	
Comparison of endotracheal tube and thin catheter for surfactant therapy in neonates with respiratory distress syndrome	
Purpose	
Treatment	
Inclusion/Exclusion criteria	
Inclusion criteria:	
Infants born with a gestational age of 25 to 37 weeks admitted to the NICU	
Exclusion criteria:	
Respiratory distress due to cardiac causes hemodynamic instability sepsis and any cause other than surfactant deficiency	
Age	
From 1 day old to 30 days old	
Gender	
Both	
Phase	
3	
Groups that have been masked	
Data analyser	
Sample size	
Target sample size: 80	
Randomization (investigator's opinion)	
Randomized	
Randomization description	
In this study, we will use the restricted randomization method of block randomization. Blocking is usually used to balance the number of samples assigned to each group. The number of samples assigned to each group is equal, and we will have 80 participants in each group. The size of all blocks is equal, and in this two-group experiment, we will have 10 blocks (including 8 participants in the intervention group and 8 participants in the control group). The drug will then be given to patients based on the blocks obtained and in the order of allocation. For randomization, it also uses random allocation software that this random sequence generation software, in addition to simple randomization, can generate a random sequence by blocking method.	
Blinding (investigator's opinion)	
Single blinded	
Blinding description	
The blinding method in this study will be single-blind. The single-blind is used to reduce bias related to the intervention and evaluate the consequences. In this study, the data analyzer will not be informed about grouping	
Placebo	
Not used	
Assignment	
Parallel	
Other design features	
Secondary Ids	
empty	
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Shiraz University of Medical Sciences
Street address	Zand street, Shiraz university of medical sciences, Shiraz, Iran
City	Shiraz
Province	Fars
Postal code	۷۱۳۳۶ ۷۱۳۴۸
Approval date	2022-01-04, 1400/10/14
Ethics committee reference number	IR.SUMS.MED.REC.1400.509
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	Treatment of respiratory distress syndrome
Timepoint	Evaluate respiratory condition of neonates at birth up to 30 days after birth
Method of measurement	Evaluate the duration and amount of need for mechanical ventilation, NCPAP and FiO2
Secondary outcomes	
empty	
Intervention groups	
1	
Description	Intervention group 1: In this study, Beraksurf surfactant (Teksima Pharmaceutical Company, Iran) was used to treat newborns. The concentration of phospholipids in

Beraksurf is 25 mg/ml. The first group will receive surfactant by INSURE and ETT method. Neonates in this group were first intubated, and then surfactant was administered to them through a suitable tracheal tube. For infants, surfactant was administered slowly through the endotracheal tube (ETT). The administration was stopped if the surfactant returned to the ETT or the patient showed signs of intolerance. Patients were extubated immediately after finishing surfactant administration through INSURE. The dosage of surfactant in this method was also 100 mg/kg

Category

Treatment - Drugs

2

Description

Intervention group 2: In this study, Beraksurf surfactant (Teksima Pharmaceutical Company, Iran) was used to treat newborns. The concentration of phospholipids in Beraksurf is 25 mg/ml. The second group will receive surfactant by MIST technique. A 5 Fr polyurethane catheter was used for these infants. Direct laryngoscopy or video laryngoscopy was used if needed, according to the doctor's opinion. The required depth for babies with a weight ≥ 1 kg was calculated using the baby's weight (kg) plus 6. The required depth for babies < 1 kg was considered between 5.5 and 6 cm. During the intervention, sedatives and painkillers were not prescribed. Infants were under CPAP during the intervention. The dosage of surfactant in this method was 100 mg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee Hospital

Full name of responsible person

Mehrdad Rezaei

Street address

Zand street, Nemazee Hospital

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2

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Rezaei

Position

Assistant professor of Shiraz university of medical sciences

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

Undecided - It is not yet known if there will be a plan to make this available