

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)

Phone

+98 71 3612 2218

Email address

md_rezaie@yahoo.co.uk

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

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4298

Email

md_rezaie@yahoo.co.uk

2

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Mehrdad Rezaei

Street address

Chamran Blvd, Hafez Hospital

City

Shiraz

Province

Fars

Postal code

7194634786

Phone

+98 71 3647 9531

Email

md_rezaie@yahoo.co.uk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahtab Memarpour

Street address

7th floor, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5417

Email

vcrdep@sums.ac.ir

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

Neonatal and Pediatrics

Street address

Zand street, Nemazee hospital

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4298

Email

md_rezaie@yahoo.co.uk

Person responsible for scientific 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

Neonatal and pediatrics

Street address

Zand street, Nemazee hospital

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4298

Email

md_rezaie@yahoo.co.uk

Person responsible for updating data

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

Neonatal and pediatrics

Street address

Zand street, Nemazee hospital

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4298

Email

md_rezaie@yahoo.co.uk

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