Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study of the effectiveness of administering surfactant by a (LISA) with a standard (invasive) method in premature infants with RDS

Protocol summary

Study aim
The aim of this study was to investigate the feasibility and potential benefits of the LISA method in premature infants on continuous positive airway pressure N-CPAP compared to the usual surfactant injection method (INSURE).

Design
A total of 120 infants with a gestational age of 28 to 34 weeks diagnosed with moderate RDS were included in the study. They were randomly divided into two groups: the group with standard treatment (aggressive) and the intervention group (less aggressive).

Settings and conduct
This randomized clinical trial will be conducted in the care department of Shahid Sadoughi Hospital.And the effectiveness of surfactant injection in two groups was compared with standard treatment (invasive) and intervention (less invasive).

Participants/Inclusion and exclusion criteria
All babies with GA = 28-34 weeks who are AGA and have RDS (respiratory score greater than 5) and CPAP pressure > 6 cm H2O, oxygen (FiO2) > 40%,

Intervention groups
Surfactant was injected into the group with the standard invasive INSURE method (n=60) using the usual method inside the tracheal tube, and surfactant was injected into the intervention group with the less invasive LISA method using N-CPAP.

Main outcome variables
Frequency of need for surfactant injection, respiratory failure, incidence of IVH, lung bleeding, pneumothorax, time to start assisted feeding, incidence of sepsis,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230326057775N1**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

Registration date

2023-10-09, 1402/07/17

Registrant information

Name

sedigheh ekraminasab

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-05, 1401/05/14

Expected recruitment end date

2023-12-10, 1402/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effectiveness of administering surfactant by a (LISA) with a standard (invasive) method in premature infants with RDS

Public title

Use of less invasive method in administering surfactant

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All babies with GA = 28-34 weeks Have RDS (respiratory score greater than 5) CPAP pressure > 6 cm H2O
Exclusion criteria:
Babies with chromosomal abnormalities Major congenital anomalies Oxygen (FiO2) > 40%
Age
From **1 day** old to **1 day** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Infants who meet the criteria for entering the study, using the random number table and PASS15 software, the numbers of the samples are announced to the researcher by the statistical consultant, and based on that, the sample is placed in one of the study groups. Randomization of the samples in the two groups under investigation is divided into two groups using the Random allocation software and using the random permutation block method.
Blinding (investigator's opinion)
Single blinded
Blinding description
All infants are under n-cpap ventilation before surfactant injection. Only the surfactant injection method will be different in the two groups, and the researcher responsible for implementing the plan (neonatal specialist flu) will be aware of the injection method along with the assistant nurse. In infants who underwent LISA. During surfactant injection, they are subjected to oxygen therapy by n-cpap method continuously. In the invasive method, after intubation and surfactant injection, the patient's tracheal tube is removed and then he undergoes n-cpap again. All other tasks are the same in both groups. The only difference between the two groups is in the surfactant administration method.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd
Street address
WJPN office, Mother and Newborn Health Research Center, Shahid Sadoughi Hospital, Ebne Sina Ave., Shahid Ghandi Blvd., Safaeyeh, Yazd, Iran
City
Yazd
Province
Yazd
Postal code
8915887857
Approval date
2022-01-11, 1400/10/21
Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.355

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
The frequency of surfactant injection
Timepoint
Depending on the need for surfactant, every few hours or every few days
Method of measurement
Number of injections

2

Description
Time to start supplemental feeding
Timepoint
How many days after birth did the feeding start?
Method of measurement
Day

3

Description
Duration of mechanical ventilation
Timepoint
day
Method of measurement

Based on the number of days required for ventilation

Secondary outcomes

1

Description
Incidence of Retinopathy of prematurity (ROP)
Timepoint
Initial screening will be done as soon as possible and followed up for up to 3 months.
Method of measurement
Eye examination by a retina specialist

2

Description
Incidence of bronchopulmonary dysplasia (BPD)
Timepoint
After 28 days, it is checked daily
Method of measurement
Based on oxygen requirement and ventilator dependence

Intervention groups

1

Description
Intervention group: In the intervention group, the less invasive method (LISA) is used for surfactant injection, and the endotracheal tube, which is an invasive method, is not used. In the LISA method, direct laryngoscopy is first performed and then an f5 NG-tube is inserted to the desired depth with Magill forceps.
Category
Treatment - Devices

2

Description
Control group: (control group or standard treatment group) In this group, the conventional invasive method with an endotracheal tube is used for surfactant injection. First, the baby is intubated, then the surfactant solution is drawn with a dose of 200 mg/kg in a 5-10 cc syringe that has been prepared in advance. and then it is injected into the tracheal tube within two minutes.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU of Shahid Sadoughi hospital in Yazd
Full name of responsible person
Mahdieh Saberi Anari
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WJPN office, Mother and Newborn Health Research Center, Shahid Sadoughi Hospital, Ebne Sina Ave., Shahid Ghandi Blvd., Safaeyeh, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abargouei
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Central building of Shahid Sadoughi University of Medical Sciences; Shahid Dr. Bahonar Square
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dvc.research@ssu.ac.ir
Web page address
https://research.ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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

Yazd University of Medical Sciences

Full name of responsible person
Mahdieh Saberi Anari

Position
Non-faculty specialist doctor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Assistant Researcher

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Master

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Hematology

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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