Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of two method surfactant administration: Minimally invasive surfactant therapy)MIST) versus InSurE (Intubation, surfactant administration and extubation) in preterm neonates with respiratory distress syndrome: A randomized controlled trial

Protocol summary

Study aim
Evaluation of the effect of two method surfactant administration: Minimally invasive surfactant therapy(MIST) versus InSurE (Intubation, surfactant administration and extubation) in preterm neonates with respiratory distress syndrome: A randomized controlled trial

Design
The design of this research was as a parallel study. In terms of blinding, it is double blinded, which will be performed on 180 patients. Block randomization method is used for randomization of patients in the control group (InSurE) or MIST

Settings and conduct
Premature infants with a gestational age of 26 to 34 weeks with respiratory distress syndrome and requiring the administration of surfactants that are otherwise healthy are randomly divided into two groups and will be compared in terms of severity of clinical symptoms based on respiratory distress grading. The neonatal intervention group first escaped under the nasal CPAP and then underwent direct laryngoscopy to receive surfactant and a feeding tube was inserted into the infant's trachea and then while the infant was breathing spontaneously it was administered. In the control group, the infant is first placed under the nasal CPAP, then intubated to administer the surfactant and receives the same amount of surfactant through the endotracheal tube, and after the endotracheal tube is stabilized, the nasal CPAP is established. Therapeutic outcomes, complications and mortality during hospitalization are measured in two groups and then compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: preterm neonates with respiratory distress syndrome; Exclusion criteria: Congenital anomaly, need for mechanical ventilation at birth, congenital infection, asphyxia, need for artificial ventilation, congenital heart disease

Intervention groups
MIST

Main outcome variables
duration of need for mechanical ventilation, duration of oxygen therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220401054389N1**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-24, 1401/03/03**
Update count: **0**

Registration date
2022-05-24, 1401/03/03

Registrant information

Name
Maryam Behmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3840 0001

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behmadim4001@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of two method surfactant administration: Minimally invasive surfactant therapy)MIST) versus InSurE (Intubation, surfactant administration and extubation) in preterm neonates with respiratory distress syndrome: A randomized controlled trial

Public title
Effect of two method surfactant administration on preterm neonates with respiratory distress syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm neonates of 26 to 34 weeks with respiratory distress syndrome
Exclusion criteria:
Preterm neonates of 26 to 34 weeks with respiratory distress syndrome
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, Block randomization random allocation will be used as a reliable randomization method that leads to a balanced allocation of individuals in treatment groups at the end of each block. For this purpose, a list of random blocks is prepared using Random Allocation Software. Then according to the order of the contents of the blocks, which includes the group name and patient number, each patient is assigned to one of the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Upon the neonate's visit, the nurse accidentally opens one of the blocks, without knowing the allocations, presents one of the numbers to the neonatal fellowship, which is aware of the group type. It will be evolutionarily followed up in 4 times by a resident who does not know the allocation. Data registration in SPSS is done as groups A and B and the data analyzer does not know the intervention or control group. The follower and analyzer is not aware of the group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ethics committee-Ghoreishi building- Daneshgah Ave, Mashhad
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Razavi Khorasan
Postal code
9919991766
Approval date
2022-04-09, 1401/01/20
Ethics committee reference number
IR.MUMS.REC.1401.012

Health conditions studied

1

Description of health condition studied
respiratory distress syndrome
ICD-10 code
KB23.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Duration of oxygen therapy
Timepoint
Duration of hospitalization
Method of measurement
Number of hours of oxygen therapy after surfactant administration

Secondary outcomes

1

Description
Duration of need for respiratory support
Timepoint
During and after the administration of surfactant until discontinuation of respiratory support
Method of measurement
Number of hours of need for respiratory support

Intervention groups

1

Description
Intervention group: Minimally invasive surfactant therapy(MIST)
Category
Treatment - Devices

2

Description
Control group: Intubation (INSURE (Intubation, surfactant administration and extubation))
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Educational Research and Treatment Center
Full name of responsible person
Maryam Behmadi
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2

Recruitment center
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Sponsors / Funding sources

1

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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
Mashhad 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
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Full name of responsible person
Maryam Behmadi

Position
Neonatal Medicine Resident
Latest degree
Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The research team has no plans to publish the IPD
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available