Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison prognosis the effect of two methods surfactant administration: Minimally invasive surfactant therapy(MIST) versus InSurE (Intubate, surfactant administration and extubate) in preterm neonates with respiratory distress syndrome at two year

Protocol summary

Study aim

Determining the effect of two methods of surfactant administration (MIST with InSurE method)) in infants with respiratory distress syndrome on the development of two years old

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 148 patients. Random Allocation Software is used for randomization.

Settings and conduct

In a double-blind clinical trial, we randomly assigned a preterm infant with a RDS and a need for surfactant born in the maternity ward and operating room of Ghaem Hospital in Mashhad to two intervention (MIST) and control groups (InSurE). We divide the follower and statistical analyst is not aware of the groups. we will follow these infants in terms of mortality and development until the age of two, and finally the two groups are compared based on the type of surfactant received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants with RDS with gestational age 26 to 34 weeks need surfactant
Conditions of absence: congenital anomaly or infection, history of developmental delay in the family

Intervention groups

In the neonatal under NCPAP intervention group, laryngoscopy was performed directly to receive surfactant and a feeding tube No. 5F was inserted and fixed in the infant's trachea, and then while the infant was breathing spontaneously, 100 mg/kg body weight of beractant was administered through the feed tube, during 1- 3 minute. Then the feed tube is removed and the NCPAP is continued. In the control group, the infant underwent NCPAP to administer surfactant and received the same amount of surfactant through the endotracheal tube. After the neonatal condition was adjusted, the tube was removed and NCPAP was re-established.

Main outcome variables

The need for mechanical ventilation as a primary outcome and two-year prognosis as a secondary outcome are compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110807007244N8**
Registration date: **2022-06-11, 1401/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-11, 1401/03/21**
Update count: **0**

Registration date

2022-06-11, 1401/03/21

Registrant information

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Hassan Boskabadi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-06-07, 1401/03/17
Expected recruitment end date
2024-07-07, 1403/04/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison prognosis the effect of two methods surfactant administration: Minimally invasive surfactant therapy(MIST) versus InSurE (Intubate, surfactant administration and extubate) in preterm neonates with respiratory distress syndrome at two year

Public title
Comparison of the evolution of the effect of the two methods of prescribing the mature substance to the lungs of premature infants: Delicate endotracheal catheter during spontaneous respiration with intratracheal intubation in infants at two years of age
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Premature infants with respiratory distress syndrome with a gestational age of 26 to 34 weeks require surfactant
Exclusion criteria:
Congenital anomaly Requires mechanical ventilation in the delivery room Congenital infection Asphyxia Congenital heart disease History of developmental delay
Age
From **1 day** old to **24 months** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **148**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The main researcher following the neonatal follow-up, the data collectors and the data analyzers are not aware of the groups.
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
NICU, Ghaem Hospital, Ahmadabad St, Mashhad
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Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Approval date
2021-05-10, 1400/02/20
Ethics committee reference number
IR.MUMS.REC.1401.012

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome of newborn
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Duration of need for respiratory support
Timepoint
During hospitalization
Method of measurement
Number of days of need for respiratory support

Secondary outcomes

1

Description
Two years development
Timepoint
24 monthly
Method of measurement
Denver Test 2

Intervention groups

1

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

2

Description
Control group: 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
Hassan Boskabadi
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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
Mashhad University of Medical Sciences
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Position
Professor
Latest degree
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Other areas of specialty/work
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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
There is not a plan to make this available

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