

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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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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

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Ethics committee-Ghoreishi building- Daneshgah Ave, Mashhad

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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

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Full name of responsible person

Maryam Behmadi

Position

Neonatal Medicine Resident

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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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

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