Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of minimally invasive surfactant therapy (MIST) vs Intubation, Surfactant administration and Extubation (INSURE) method in neonatal respiratory distress of preterm neonates with 34 weeks or less

Protocol summary

Summary

(1) Objectives: comparison of the effect of two methods for injection of MIST vs INSURE in neonates with RDS (2) Design : 50 Preterm infants (28-34 weeks of gestation) born with respiratory distress syndrome in Arash Hospital were randomly allocated to two 25 groups to receive 200 mg/kg of surfactant using either the MIST or INSURE techniques (4) Participants including major eligibility criteria: Inclusion criteria: Preterm neonates between 28 to 37 weeks with RDS. Exclusion criteria: parents have not consent with incorporating in study; neonates with asphyxia (5) Intervention: 25 participants take 200 mg/kg surfactant by MIST method and another group receives same quantity of surfactant by INSURE method (6) Primary outcome:Duration of Oxygen Consumption, Apnea and Need for second dose surfactant and secondary outcome:The rate of intubated in First 72 h of Life, Length of Stay in NICU, Death and Complications of surfactant injection (Coughing or Gagging, Pneumothorax, Surfactant Reflux, Bradycardia, Pulmonary Hemorrhage, Intra ventricular Hemorrhage (>grade 2))

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080716937N4**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Zohreh Farsi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3284

Email address

mosayebi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-04-01, 1392/01/12

Expected recruitment end date

2014-02-28, 1392/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of minimally invasive surfactant therapy (MIST) vs Intubation, Surfactant administration and Extubation (INSURE) method in neonatal respiratory distress of preterm neonates with 34 weeks or less

Public title

Study of the effect of surfactant in respiratory distress of preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: preterm neonates with 34 week age or less; respiratory distress due to surfactant deficiency; Exclusion criteria: parents have not consent with incorporating in study; neonate with asphyxia; neonates with intubation from the birth; respiratory distress not due to RDS; neonates with maternal abnormality

Age

To **1 month** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Randomization is done by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, Tehran, Tehran Province, Iran

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

117813-9111403006

Health conditions studied

1

Description of health condition studied

Respiratory distress of newborn

ICD-10 code

p22.9

ICD-10 code description

Respiratory distress of newborn, unspecified

Primary outcomes

1

Description

Need for second dose surfactant

Timepoint

Per 6 hour after intervention

Method of measurement

Chart

2

Description

Apnea

Timepoint

During hospitalization

Method of measurement

Visit

3

Description

Duration of Oxygen Consumption

Timepoint

Per 6 hour after intervention

Method of measurement

Chart

Secondary outcomes

1

Description

Complications of surfactant injection (Coughing or Gagging, Pneumothorax, Surfactant Reflux, Bradycardia, Pulmonary Hemorrhage, Intra ventricular Hemorrhage (>grade 2))

Timepoint

Per 6 hour after intervention

Method of measurement

Chart and visit

2

Description

The rate of intubated in First 72 h of Life

Timepoint

Per 6 hour after intervention

Method of measurement

Chart

3

Description

Length of Stay in NICU

Timepoint

Per 6 hour after intervention
Method of measurement
Chart

4

Description
Death
Timepoint
During hospitalization
Method of measurement
Chart

Intervention groups

1

Description
participants take 200 mg/kg surfactant by MIST method
Category
Treatment - Drugs

2

Description
participants take 200 mg/kg surfactant by INSUR method
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash hospital
Full name of responsible person
Zohreh Farsi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zohreh Farsi
Street address
Alley No169, St. Baghdarniya, Bagheri Highway, Resalat Highway
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences (Arash hospital)
Full name of responsible person
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Position
neonatologist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty