

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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**  
Zohreh Farsi  
**Position**  
neonatologist  
**Other areas of specialty/work**  
**Street address**  
Alley No169, St. Baghdarniya, Bagheri Highway,  
Resalat Highway  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 7788 3284  
**Fax**  
**Email**  
sh.farsi@yahoo.com  
**Web page address**

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences (Arash hospital)  
**Full name of responsible person**  
Zohreh Farsi  
**Position**  
neonatologist  
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**Web page address**

## Person responsible for updating data

### 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****Street address**

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**City**

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**Postal code****Phone**

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**Fax****Email**

sh.farsi@yahoo.com

**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*