

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial on the effectiveness of surfactant administration via a thin intratracheal catheter (Insure method) and intubation during spontaneous breathing in premature neonates.

#### Protocol summary

##### Summary

Objective: To compare the effectiveness of surfactant administration via a thin intratracheal catheter (Insure method) and intubation during spontaneous breathing in premature neonates. Design: A single-blinded, block randomized clinical trial. Study population: Premature infants with the respiratory distress syndrome. Inclusion criteria: Premature infants with the respiratory distress syndrome; premature birth less than 32 weeks of gestational age; birth weight less than 1500 g. Exclusion criteria: Congenital anomalies; requiring mechanical ventilation after birth; infants with underlying disease (congenital infections, asphyxia, congenital cardiac defect). Sample size: 40 cases. Study intervention: The intervention group is receiving 100 mg/kg surfactant in 1-3 minutes via a thin intratracheal catheter (Insure method) during spontaneous breathing. The control group is receiving surfactant via intubation by positive pressure ventilation with the same dosage. Study outcome: To compare the effectiveness of two methods on duration of mechanical ventilation and morbidity and mortality rate in premature neonates 24 hours after intervention in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016061328422N1**  
Registration date: **2016-06-20, 1395/03/31**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-06-20, 1395/03/31

#### Registrant information

##### Name

Reza Gharaei

##### Name of organization / entity

Emam Reza Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3854 3031

##### Email address

gharaei@ums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

#### Expected recruitment start date

2016-07-31, 1395/05/10

#### Expected recruitment end date

2017-09-01, 1396/06/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Clinical trial on the effectiveness of surfactant administration via a thin intratracheal catheter (Insure method) and intubation during spontaneous breathing in premature neonates.

#### Public title

Treatment of premature infants during spontaneous breathing

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Premature infants with the respiratory distress syndrome; premature birth less than 32 weeks of gestational age; birth weight less than 1500 g.  
Exclusion criteria: Congenital anomalies; requiring mechanical ventilation after birth; infants with underlying disease (congenital infections, asphyxia, congenital cardiac defect).

## Age

From **1 day** old to **1 day** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## 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

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

##### City

Mashhad

##### Postal code

#### Approval date

2013-10-19, 1392/07/27

#### Ethics committee reference number

IR.MUMS.REC.1392.163

## Health conditions studied

### 1

#### Description of health condition studied

Respiratory distress syndrome

#### ICD-10 code

P22.0

#### ICD-10 code description

Respiratory distress syndrome of newborn

## Primary outcomes

### 1

#### Description

Duration of mechanical ventilation

#### Timepoint

24 hours after intervention

#### Method of measurement

Day

## Secondary outcomes

### 1

#### Description

Morbidity and mortality rate in premature neonates

#### Timepoint

24 hours after intervention

#### Method of measurement

Case

## Intervention groups

### 1

#### Description

Control group: Neonatal intubation and who are receiving 100 mg/kg surfactants in 1-3 minutes via a feeding tube.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Who are receiving 100 mg/kg surfactant in 1-3 minutes from a feeding tube via a thin intratracheal catheter (Insure method) during spontaneous breathing.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Reza Gharaei

##### Street address

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue

##### City

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Mashhad 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**

Emam Reza Hospital

**Full name of responsible person**

Hassan Boskabadi

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue

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+98 51 3852 1121

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BoskabadiH@mums.ac.ir

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Emam Reza Hospital

**Full name of responsible person**

Reza Gharaei

**Position**

neonatologist

**Other areas of specialty/work****Street address**

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue

**City**

Mashhad

**Postal code****Phone**

+98 51 3854 3031

**Fax****Email**

gharaei@r@gmail.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*