

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Surfactant administration via laryngeal mask airway (LMA) versus endotracheal tube in neonatal respiratory distress syndrome, a randomized controlled trial

Protocol summary

Summary

In a randomized clinical trial, 60 preterm neonates with gestation age 29-37 weeks who were diagnosed with respiratory distress syndrome and require surfactant treatment, will be randomly allocated to two groups. Thirty neonates receive surfactant via endotracheal tube and 30 via laryngeal mask. Then patients will be extubated. We follow patients with respect to the need for FiO₂ to maintain normal O₂ saturation and need for intubation and assisted ventilation during the first 3 days after surfactant therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602019568N14**
Registration date: **2016-03-10, 1394/12/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-10, 1394/12/20

Registrant information

Name

Golnaz Rezaeizadeh

Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran
University of Medical Sciences, Tehran, Iran

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Recruitment status

Recruitment complete

Funding source

Research deputy of the Tehran University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surfactant administration via laryngeal mask airway (LMA) versus endotracheal tube in neonatal respiratory distress syndrome, a randomized controlled trial

Public title

surfactant administration via laryngeal mask airway versus endotracheal tube in severe neonatal respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: born at less than 37 gestational weeks, weighed $\geq$ 1200 grams, had a diagnosis of RDS within the first two hours of life, requiring continuous positive airway pressure (CPAP) support $\geq$ 5cm H₂O (with or without nasal intermittent positive pressure ventilation (PPV)), plus fraction of inspired oxygen (FiO₂) between 30 - 60% to maintain blood oxygen saturation (SpO₂) between 88 to 95% Exclusion criteria: having a previous intubation, major malformations (craniofacial, cardiac or thoracic), mean arterial pressure (MAP) < 40 mmHg, Apgar score $\leq$ 3 at 5 minutes, requiring FiO₂

concentrations > 60%, pneumothorax prior to enrollment, apnea requiring assisted ventilation, diaphragmatic hernia, and parents' refusal to give informed consent.

Age

To 3 days old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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 the Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Street

City

Tehran

Postal code**Approval date**

2015-05-10, 1394/02/20

Ethics committee reference number

IR.TUMS.REC.1394.2027

Health conditions studied**1****Description of health condition studied**

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Hyaline membrane disease

Primary outcomes**1****Description**

The requirement for mechanical ventilation

Timepoint

One hour after surfactant treatment

Method of measurement

PH<7.15, PCO₂>60, PO₂<50 on the Arterial blood gas analysis

Secondary outcomes**1****Description**

requirement for a second dose of surfactant

Timepoint

eight hours after surfactant administration

Method of measurement

Redosing was considered if FiO₂ was ≥ 60% or if FiO₂ was ≥ 30% associated with worsening of RDS clinical signs.

2**Description**

Reduced needed FiO₂ to maintain adequate oxygenation

Timepoint

Before and one hour after surfactant therapy

Method of measurement

Determination of needed Fio₂ in blender and by pulse oxymetry

Intervention groups**1****Description**

Intervention group: After inserting a size 1 Classic LMA using standard techniques, surfactant 2.5 ml/kg per dose was given in 2-4 aliquots to spontaneously breathing infants, at the distal end of the LMA using a shortened 5 French-feeding catheter.

Category

Treatment - Drugs

2**Description**

Control group: INSURE approach was used for surfactant delivery; the neonates were intubated and surfactant 2.5 ml/kg per dose was given via endotracheal tube in 2-4 aliquots.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-asr hospital

Full name of responsible person

Dr. Sajjad Nourollahi

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Golnaz Rezaeizadeh

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Maternal, Fetal and Neonatal Research Center, Vali-asr Hospital, Imam Khomeini Hospital complexes, Keshavarz blvd

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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

Maternal, Fetal and Neonatal Research Center

Full name of responsible person

Dr. Mahdi Sheikh

Position

Researcher

Other areas of specialty/work

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Associate Professor

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Position

Researcher

Other areas of specialty/work

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Phone

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Fax

Email

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