

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Email address

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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 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

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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

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

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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

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Associate Professor

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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