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

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Name of organization / entity
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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 receiving100 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
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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

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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