Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Concomitant intratracheal administration of surfactant and budesonide in the prevention of bronchopulmonary dysplasia (BPD) compared with surfactant alone in the treatment of respiratory distress syndrome in preterm infants.

Protocol summary

Study aim
Comparison of the effect of concomitant endotracheal administration of surfactant and budesonide with surfactant alone in preventing bronchopulmonary dysplasia in preterm infants

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 296 patients.A random list will be prepared by visiting the sealed envelope site.

Settings and conduct
Premature infants hospitalized in Hazrat Rasoul Akram and Shahid Akbarabadi hospitals in Tehran will be included in the study.The grouping is in a sealed envelope and is opened by the pharmacy, and the doctor receives the medicine in a syringe that has been drawn and is ready for injection and injects it into the trachea. The relevant nurse and physician who fill the checklist will not be aware of the baby's grouping.In the control group, an initial dose of Braksurf is injected into the trachea. In the intervention group, in addition to Braksurf, budesonide is injected into the trachea.

Participants/Inclusion and exclusion criteria
Admission requirements: Premature infants with a gestational age less than 37 weeks and weighing less than 1,500 g ; and requires a surfactant injection at the physician's discretion. Exclusion requirements : -Congenital major anomalies -Asphyxia -Parental dissatisfaction

Intervention groups
Intervention group: Simultaneous intratracheal injection of surfactantand and budesonide Control group: Surfactant injection

Main outcome variables
Need for additional dose of surfactant; Duration of need for mechanical ventilation; Duration of need for non-invasive ventilation; Duration of need for hospitalization; Bronchopulmonary dyspasia incidence

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211107052993N1**
Registration date: **2021-11-21, 1400/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-21, 1400/08/30**
Update count: **0**

Registration date
2021-11-21, 1400/08/30

Registrant information
Name
arezoo aminyan daryasari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 4222 9638
Email address
a.aminyan@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-10, 1400/08/19
Expected recruitment end date
2022-05-20, 1401/02/30
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Concomitant intratracheal administration of surfactant and budesonide in the prevention of bronchopulmonary dysplasia (BPD) compared with surfactant alone in the treatment of respiratory distress syndrome in preterm infants.

Public title

Concomitant intratracheal administration of surfactant and budesonide in the prevention of bronchopulmonary dysplasia (BPD)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with a Gestational age less than 37 weeks weighing less than 1,500 g Premature infants admitted to the Neonatal ward due to Respiratory distress syndrome based on clinical and radiological symptoms and negative blood culture at birth; And receives any non-invasive respiratory support, and requires a surfactant injection at the physician's discretion.

Exclusion criteria:

Congenital major anomalies that affect the baby's breathing Existence of asphyxia; (Apgar score less than 7 in 5 minutes of birth) Parental dissatisfaction Gastrointestinal abnormalities that cause the baby to be transferred to another center Congenital cyanotic heart disease

Age

To **30 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **296**

Randomization (investigator's opinion)

Randomized

Randomization description

Premature infants with symptoms of Respiratory Distress Syndrome are randomly assigned to one of two groups of control (surfactant) or intervention (surfactant plus budesonide) according to random numbers extracted from the computer. To assign each person to the study arms, a random list will be prepared by visiting the sealed envelope site. This site allows us to have a random list at the beginning of the study to assign people to study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining informed written consent from the parents of premature infants with symptoms of Respiratory Distress Syndrome, they are randomly assigned to one of two groups of control (surfactant) or intervention (surfactant plus budesonide) according to random numbers extracted from the computer. The grouping is in a sealed envelope and is opened by the pharmacy, and the doctor receives the medicine in a syringe that has been drawn and is ready for injection and injects it into the trachea. The relevant nurse and physician who records the patient information checklist will not be aware of the baby's grouping. The doctor involved in the treatment of infants does not know the grouping of infants.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.IUMS.FMD.REC.1400.165

Health conditions studied

1

Description of health condition studied

Bronchopulmonary dysplasia

ICD-10 code

P27.1

ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

2

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
Bronchopulmonary dysplasia
Timepoint
daily , end of 6 week or discharge time
Method of measurement
clinical

2

Description
duration of auxiliary oxygen reception
Timepoint
daily , end of 6 week or discharge time
Method of measurement
clinical

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Simultaneous intratracheal injection of surfactant (braksurf with an initial dose of 4 cc per kg body weight) and budesonide (budesonide at a dose of 0.25 mg / kg body weight)
Category
Prevention

2

Description
Control group: intratracheal injection of surfactant (braksurf with an initial dose of 4 cc per kg body weight
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi Hospital
Full name of responsible person
Arezoo Aminyan
Street address
Shahid Akbarabadi Medical Training Center, Ferdows Garden Station, Molavi St., Tehran, Iran
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Fax
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akbarabadihosp@yahoo.com

2

Recruitment center
Name of recruitment center
Hazrat Rasool Akram Hospital
Full name of responsible person
Arezoo Aminyan
Street address
Hazrat Rasoul Akram Hospital, Niayesh St., corner of Mansouri Kia St., Sattarkhan neighborhood, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
leyla irani
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Iran University of Medical Sciences, next to Milad Tower, Shahid Hemmat Highway, Tehran, Iran
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iumspr@ums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Arezoo Aminyan daryasari
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Sharing information about the main outcome
When the data will become available and for how long
6 months after publication
To whom data/document is available
Physicians working in scientific and academic institutions
Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

a.aminyan@yahoo.com

What processes are involved for a request to access data/document

Request by email with job description

Comments