

# 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 surfactant 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 dysplasia 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**

1429614030

**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

#### City

Tehran

#### Province

Tehran

#### Postal code

1168743514

#### Phone

+98 21 5560 6034

#### Fax

#### Email

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

Rasulhospital@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

leyla irani

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 1021

##### Email

iumspr@iums.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**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Naft building 264, Zafar Ave., Tehran, Iran

**City**

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**Province**

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**Postal code**

1918613436

**Phone**

+98 13 4222 9638

**Fax****Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Arezoo Aminyan daryasari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data****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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**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**