# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 2026

## A Comparative Study of Concomitant Intratracheal Administration of Surfactant with Budesonide with Surfactant alone in Premature Infants with Respiratory Distress Syndrome.

## Protocol summary

**Study aim**

Comparison between effects administration of intratracheal surfactant and surfactant/budesonide concomitantly in preterm infants with respiratory distress syndrome in Ayatollah Mousavi Hospital in Zanjan.

**Design**

Clinical trial with control group, with parallel group,Not Blinded, Randomised trial with random sequencing on 134 patients.

**Settings and conduct**

All premature infants born with gestational age less than 37 weeks of gestation who have respiratory distress syndrome and are admitted in neonatal intensive care unit of Ayatollah Mousavi Hospital in Zanjan enter in one of control or intervention groups and then based on the prepared checklist, information about the variables are recorded and evaluated.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria included premature infants below 37 week's of gestation with moderate to severe Respiratory Distress Syndrome and: Weight less than 2500 grams; Need to mechanical ventilation; Need to inhale more than 30% oxygen for below 28 weeks of gestation and more than 40% in above 28 weeks of gestation.
Exclusion criteria included: Weight less than 700 grams; Severe congenital anomaly; Fatal cardiopulmonary disease; Other causes respiratory distress such as Congenital Diaphragmatic Hernia.

**Intervention groups**

In the control group, neonates receive intratracheal Surfactant at a dose of 2.5 cc/kg and in the intervention group, neonates were traeted with intratracheal Surfactant 2.5 cc/kg mixed by 1 cc/kg of Budesonide solution.

**Main outcome variables**

Incidence of death; Bronchopulmonary dysplasia; Duration of mechanical ventilation; Need the next doses surfactant; Length of hospital stay; oxygen index on the first and third days of treatment; Mean airway pressure on the first and third days of treatment; Incidence of pneumothorax; Pulmonary hemorrhage; Intracerebral hemorrhage; Mean systolic and diastolic blood pressure; Blood sugar.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201222049802N1**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

**Registration date**

2021-02-28, 1399/12/10

**Registrant information**

**Name**
Asghar Marzban
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-01-04, 1399/10/15

**Expected recruitment end date**

2021-03-15, 1399/12/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Comparative Study of Concomitant Intratracheal Administration of Surfactant with Budesonide with Surfactant alone in Premature Infants with Respiratory Distress Syndrome.

**Public title**

A Comparative Study of Concomitant Intratracheal Administration of Surfactant with Budesonide with Surfactant alone in Premature Infants with Respiratory Distress Syndrome.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Premature Infant Less than 37 week's with Moderate or severe RDS Weight less than 2500 grams Requires Mechanical Ventilation Requires FiO2 more than 30% at Gestational age under 28 week's and more than 40% at Gestational age more than 28 week's.

**Exclusion criteria:**

Weight Less than 700 grams Severe Congenital Anomalies Fatal Cardiopulmonary Disease Other causes for Respiratory Distress Include Congenital Diaphragmatic Hernia

**Age**

To **3 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **134**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomized by random sequencing on 134 patients. For this aim we used from random allocation method (by the method of variable blocks).

**Blinding (investigator's opinion)**

Not 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 Zanjan University of Medical Sciences

**Street address**

Ayatollah Mousavi Hospital, Above Shahid Sabouti Boulevard, Gavazang Road, Zanjan, Iran.

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956183

**Approval date**

2020-10-29, 1399/08/08

**Ethics committee reference number**

IR.ZUMS.REC.1399.271

## Health conditions studied

### 1

**Description of health condition studied**

Respiratory distress syndrome of newborn

**ICD-10 code**

P22.0

**ICD-10 code description**

Respiratory distress syndrome of newborn

## Primary outcomes

### 1

**Description**

Incidence of death

**Timepoint**

Incidence of death from admission to hospital discharge.

**Method of measurement**

Physical examination

### 2

**Description**

Incidence of Bronchopulmonary Dysplasia

**Timepoint**

Evaluation of Diagnostic criteria of Bronchopulmonary Dysplasia at 14 and 28 days after the start of the study.

**Method of measurement**

Evaluation of Diagnostic criteria

### 3

**Description**

Duration of hospitalization

**Timepoint**

At the time of discharge from the hospital

**Method of measurement**

Count the number of hospitalization days

**4**

**Description**
Duration requires Mechanical ventilation
**Timepoint**
From patient admission to hospital discharge
**Method of measurement**
Count the days required for a mechanical ventilation

**5**

**Description**
Incidence of Pneumothorax
**Timepoint**
From patient admission to hospital discharge
**Method of measurement**
Clinical observation and chest x ray.

**6**

**Description**
Incidence of pulmonary hemorrhage
**Timepoint**
From patient admission to hospital discharge
**Method of measurement**
Clinical observation and chest x ray

**7**

**Description**
Incidence of Intraventricular hemorrhage
**Timepoint**
At 7, 14 and 30 days if hospitalized.
**Method of measurement**
Brain Sonography

**8**

**Description**
Oxygen index on the first and third day of treatment
**Timepoint**
the first and third day of treatment
**Method of measurement**
Calculated using the formula. Mean airway pressure multiplied by fraction of Inspired oxygen divided by arterial oxygen pressure multiplied by 100.

**9**

**Description**
Mean airway pressure on the first and third day of treatment
**Timepoint**
the first and third day of treatment
**Method of measurement**
Using the number calculated by the Ventilator

**10**

**Description**
Need the next dose of Surfactant
**Timepoint**
The first three days of hospitalization
**Method of measurement**
Record patient file information.

**11**

**Description**
Mean systolic and diastolic blood pressure
**Timepoint**
The first and third day of treatment
**Method of measurement**
Using an oscillometric barometer attached to the monitor

**12**

**Description**
Blood Sugar level
**Timepoint**
The first and third day of treatment
**Method of measurement**
Using a Glucometer

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: hospitalized infants receive 2.5 cc/kg Curosurf vial in combination with 1 cc/kg Pulmicort inhaler solution. Curosurf is a natural surfactant. each vial of Curosurf (Poractant alfa) used in this trial 3cc instillation suspension with contains 240mg phospholipid fraction from Porcine lung. ( Made by Chiesie Pharma company of Italy). The recommended starting dose is 100-200 mg/kg ( 1.25- 2.5ml/kg), additional doses of 100mg/kg (1.25 ml/kg), each at about 6-12hourly intervals may also be administered if needed. Pulmicort inhaler solution used in this trial is 2cc suspension with 0.25 mg/ml concentration containing Budesonide. (Made by Swedish manufacture ASTRAZENECA which is imported by Cobel Daru company). The vials should be warmed to room temperature by holding it in the hand for a few minutes, before use, and gently turned upside down a few times, without shaking, in order to obtain a uniform suspension. The suspensions should be withdrawn from the vials using a sterile needle and syringe and mixed gently. A suitable tube should then be used to instill Curosurf with Budesonide into the lung directly into the lower trachea by passing a catheter through the tube after intubation of patient.
**Category**
Treatment - Drugs

**2**

**Description**
Control group:hospitalized infants receive Curosurf vial alone. Curosurf is a natural surfactant. each vial of Curosurf (Poractant alfa) used in this trial 3cc instillation suspension contains 240mg phospholipid fraction from Porcine lung. (Made by Chiesie Pharma company of

Italy). The recommended starting dose is 1.25 - 2.5ml/kg and additional doses is 1.25 ml/kg, each at about 6-12hourly intervals may also be administered if needed. The vial should be warmed to room temperature by holding it in the hand for a few minutes before to use, The suspension should be withdrawn from the vial using a sterile needle and syringe. A suitable tube should then be used to instill Curosurf into the lung directly into the lower trachea by passing a catheter through the tube after intubation of patient.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Ayatollah Mousavi hospital
**Full name of responsible person**
Samira Mokhtari
**Street address**
Ayatollah Mousavi Hospital, Gavazang Ave, Shahid Sabouti Blvd, zanjan, iran.
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Mousavihospital@zums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Zanjan University of Medical Sciences
**Full name of responsible person**
Alireza Shoghli
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Zanjan University Of Medical Science
**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**
Zanjan University of Medical Sciences
**Full name of responsible person**
Asghar Marzban
**Position**
Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available