Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1292

Email address

drmarzban@zums.ac.ir

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.
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3342 0651
Fax
+98 24 3313 1203
Email
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
Street address
Ayatollah Mousavi Hospital, Gavazang Ave, Shahid Sabouti Blvd, zanjan, iran.
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3342 0651
Email
Mousavihospital@zums.ac.ir

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
Pediatrics
Street address
Ayatollah Mousavi Hospital, Gavazang Ave, Shahid Sabouti Blvd, zanjan, iran.
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3342 0651
Email
Drmarzban@zums.ac.ir

Person responsible for scientific 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
Pediatrics
Street address
Ayatollah Mousavi Hospital, Gavazang Ave, Shahid Sabouti Blvd, zanjan, iran.
City

Zanjan

Province
Zanjan

Postal code
4513956183

Phone
+98 24 3342 0651

Email
Drmarzban@zums.ac.ir

Person responsible for updating data

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
Pediatrics

Street address
Ayatollah Mousavi Hospital, Gavazang Ave, Shahid Sabouti Blvd, zanjan, iran.

City
Zanjan

Province
Zanjan

Postal code
4513956183

Phone
+98 24 3342 0651

Email
Drmarzban@zums.ac.ir

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