

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative survey of the consequences of intratracheal administration of surfactant and surfactant with budesonide in premature infants with respiratory distress syndrome

Protocol summary

Study aim

Determination of the consequences of intratracheal administration of surfactant and surfactant with budesonide in premature infants with respiratory distress syndrome, hospitalized in the neonatal intensive care unit of Kosar Hospital in Qazvin in 2019 year

Design

The clinical trial as a comparative study, with a control group, with parallel, randomized, single-center groups, randomization with the checklist

Settings and conduct

In infants that are under nasal continuous positive airway pressure and ventilator, gradually flow continues increase to CDP = 6 inches, H₂O and FiO₂ = 30%. A requirement of FiO₂ more than 40% to maintain oxygen saturation in the range of 90 to 95%, surfanta is prescribed at a dose of 100 mg / kg and the infant is included in the study. If the infant needs more than 40% FiO₂ to maintain acceptable oxygen saturation, surfanta should be repeated 6 hours after the first administration. If necessary, the treatment period (4 days) is complete. Before and after the administration of the surfactant, and after that mechanical ventilation management infants are monitored for arterial blood gas and every 12 hours.

Participants/Inclusion and exclusion criteria

Entry conditions: Infants with clinical signs of respiratory distress syndrome, infants with 2 weeks age, infants with surfactant and nasal continuous positive airway pressure; No entry conditions: Infants with congenital anomalies and perinatal asphyxia.

Intervention groups

In the intervention group, surfactant is prescribed for infants. In the control group for infants, combination treatment of surfactant with budesonide 0.25 mg is administered intratracheally.

Main outcome variables

Pneumothorax, Pneumonia, Chronic Pulmonary Disease,

Intraventricular Bleeding, Periventricular Leukomalacia, Cardiac Complications, Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210412050944N1**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **prospective**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Fatemeh Tohidnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3332 8709

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cgd.rc@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-24, 1400/04/03

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative survey of the consequences of intratracheal administration of surfactant and surfactant with budesonide in premature infants with respiratory distress syndrome

Public title
Consequences of intratracheal administration of surfactant and surfactant with budesonide

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infants that have clinical signs of respiratory distress syndrome. Infants that their ages are have 2 weeks. Infants receiving nasal continuous positive airway pressure with surfactant.
Exclusion criteria:
Infants that have congenital anomalies. Infants that have perinatal asphyxia.

Age
From **1 day** old to **14 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization of patients will be done by randomization of 4 blocks (AA, BB-AB, AB-BA, BA-AA, BB). Exactly equal numbers of participants enter the groups at consecutive but equal intervals. Therefore, two groups are considered. In intervention group A patients, for 25 infants with respiratory distress syndrome, Sorvanta at a dose of 100 mg / kg and in intervention group B, for 25 infants with respiratory distress syndrome, Survanta at a dose of 100 mg/kg with budesonide 0.25 mg is administered intratracheally. The administration for each group should be repeated 6 hours after the first administration. If necessary, the treatment period is completed within 4 days. Before and after administration, neonates are tested for ABG (Arterial blood gas) separately in each group. They are then monitored for mechanical ventilation management every 12 hours. The necessary information for the study will be collected using a checklist and finally the consequences of the prescription between the two groups will be analyzed and compared.

Blinding (investigator's opinion)
Double blinded

Blinding description

In this study, health care personnel (physicians, nurses, physiotherapists, etc.) who are responsible for caring for patients and infants (or parents of infants) are blind.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Quds Educational and Medical Center, Beginning of East Palestine Ave., Shahid Beheshti Blvd., Qazvin City

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2021-02-02, 1399/11/14

Ethics committee reference number

IR.QUMS.REC.1399.386

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of infants with respiratory distress syndrome

Timepoint

Before the intervention and every 12 hours after the administration of surfactant in the intervention group and surfactant with budesonide 0.25 mg intratracheally in the control group

Method of measurement

Mechanical Ventilation Device

Secondary outcomes

1

Description

Reduction of respiratory distress syndrome in preterm infants prescribed with surfactant and surfactant with budesonide

Timepoint

Before the intervention and every 12 hours after the administration of surfactant in the intervention group and surfactant with budesonide 0.25 mg intratracheally in the control group

Method of measurement

Mechanical Ventilation Devices

Intervention groups

1

Description

Intervention group 1: In infants that are under nasal continuous positive airway pressure and ventilator, gradually flow continues increase to CDP = 6 inches, H₂O and FiO₂ = 30%. A requirement of FiO₂ more than 40% to maintain oxygen saturation in the range of 90 to 95%, surfanta with budesonide 0.25 mg intratracheally is prescribed at a dose of 100 mg / kg and the infant is included in the study. If the infant needs more than 40% FiO₂ to maintain acceptable oxygen saturation, surfanta should be repeated 6 hours after the first administration. If necessary, the treatment period (4 days) is complete. Before and after the administration the mechanical ventilation management of infants is monitored for arterial blood gas and every 12 hours monitored for arterial blood gas and every 12 hours, Intervention group 2: In infants that are under nasal continuous positive airway pressure and ventilator, gradually flow continues increase to CDP = 6 inches, H₂O and FiO₂ = 30%. A requirement of FiO₂ more than 40% to maintain oxygen saturation in the range of 90 to 95%, surfanta with budesonide 0.25 mg intratracheally is prescribed at a dose of 100 mg / kg and the infant is included in the study. If the infant needs more than 40% FiO₂ to maintain acceptable oxygen saturation, surfanta should be repeated 6 hours after the first administration. If necessary, the treatment period (4 days) is complete. Before and after the administration, the mechanical ventilation management of infants is monitored for arterial blood gas and every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fatemeh Tohidnia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main consequences and variables will be presented in the form of a published article.

When the data will become available and for how long

Access period starts from 1400

To whom data/document is available

Researchers working in academic and scientific institutions, pharmacists and doctors

Under which criteria data/document could be used

For therapeutic uses, it can be used with the permission of the authors of the article and by mentioning the source.

From where data/document is obtainable

Qazvin, Shahid Beheshti Blvd, Beginning of East Palestine, Qods Square, Qods Educational and Medical Center, Postal Code: 34197-59811, E-mail: cgd_rc@yahoo.com, Phone Number: 028-33328709, Fatemeh Tohidnia

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

Phone calls, send demand to email and bring up the reason they want information, presented by other authors, if approved after a month will be sent.

Comments