Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of intratracheal injection of surfactants with and without prescription of inhalant budesonide on the clinical course of premature newborns weighing less than 1500 grams with respiratory distress syndrome in the neonatal intensive care unit. A randomized clinical trial.

Protocol summary

Summary

In this double-blind study, the effect of prescription of inhaled budesonide intact with surfactant on the clinical course of premature infants with respiratory distress syndrome was evaluated. Neonates entering the study were premature infants less than 1500 grams in weight with respiratory distress syndrome, required a surfactant and were treated with continuous airway pressure and receive oxygen more than 40 percent. Infants weighing less than 1000 gr, more than twins, have congenital malformations or have asphyxia were excluded from the study. Patients were divided into two groups. In one group, budesonide was combined with surfactant and in the other group alone, surfactant were prescribed. Infants were randomly assigned to each of the intervention or control groups and the provider, prescriber, and decision-maker were different people who were not aware of the overall study process. Treatment failure cases by the method of INSURE (INtubation, SUrfactant administration, Rapid Extubation), the duration of ventilator or c-pap requirement, the duration of oxygen requirement and the number of deaths in these two groups were compared and the relation between prescription of inhaled budesonide on the respiratory distress syndrome clinical course was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017053034219N1**
Registration date: **2017-07-20, 1396/04/29**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-07-20, 1396/04/29

Registrant information

Name

Reza babapour

Name of organization / entity

Jondi Shapoor University of Medical Sciences, Ahvaz

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Recruitment status

Recruitment complete

Funding source

The research department of Jondi Shapoor University of Medical Sciences

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-07-11, 1396/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intratracheal injection of surfactants with and without prescription of inhalant budesonide on the clinical course of premature newborns weighing less than 1500 grams with respiratory distress syndrome in the

neonatal intensive care unit. A randomized clinical trial.

Public title
The effect of inhalant budesonide with surfactant prescription in the treatment of respiratory distress syndrome in premature infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (All of the following) premature infants weighing less than 1500 grams; have respiratory distress syndrome; require a surfactant; treated with CPAP and with FIo_2> 40%. exclusion criteria:Infants weighing less than 1000 grams; more than 2 twin pregnancies; pregnancies with birth trauma; congenital anomalies; perinatal asphyxia; neonatal transfers from other institutions.
Age
To **7 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee development of Research and Technological Department of Jondi Shapoor University of
Street address
University Campus - Department of Development and Research, Ground floor
City
ahvaz
Postal code
61357-15794
Approval date
2017-04-22, 1396/02/02
Ethics committee reference number
IR.AJUMS.REC. 1396.64

Health conditions studied

1

Description of health condition studied
neonatal respiratory distress syndrome
ICD-10 code
P22
ICD-10 code description
Respiratory distress of newborn

Primary outcomes

1

Description
Duration of respiratory support required
Timepoint
The first two weeks after the intervention
Method of measurement
Recording of the time between the onset and the end of respiratory support

2

Description
Duration of additional oxygen requirement
Timepoint
The first two weeks after the intervention
Method of measurement
Recording of the time between the onset and the end of oxygen therapy

Secondary outcomes

1

Description
Length of stay in hospital
Timepoint
one month
Method of measurement
The time between admission and the beginning of the intervention until the end of the intervention and discharge from the hospital

2

Description
The number of deaths
Timepoint
one month

Method of measurement
The number of cases of intervention or control that died during the study

Intervention groups

1

Description
In the intervention group: budesonide (Pulmicort vials, product of Astrazenca Co., Canada) 0.25 mg / kg as endotracheal nebulizer immediately after standard treatment
Category
Treatment - Drugs

2

Description
The standard treatment control group: Curosurf surfactant Manufactured by Cheisi Co., Italy, at a rate of 2.5 ml/kg initially, and an extra dose of 1.5 ml/kg, if necessary
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini (RA) hospital, department of education
Full name of responsible person
Dr. Meisam Reza Boghrati, Resident of neonatology
Street address
24 meter street
City
ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Department of Jondi Shapoor University of Medical Sciences, Ahvaz
Full name of responsible person
Dr. Behzad Sharif Makhmalzade
Street address
Golestan boulevard, university campus
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Department of Jondi Shapoor University of Medical Sciences, Ahvaz
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Jondi Shapoor University of Medical Sciences, Ahvaz
Full name of responsible person
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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty