Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of intratracheal administration of Braksurf with curosurf on outcomes of neonates with respiratory distress syndrome admitted in intensive care unit

Protocol summary

Study aim

Comparative study of the effect of intratracheal administration of Braksurf with curosurf on outcomes of neonates with respiratory distress syndrome admitted in intensive care unit of Kamali hospital in 2019-2020

Design

A clinical trial with parallel, single-blind, randomized, phase 3 on 100 patients will be randomized using randomly sized blocks of random size.

Settings and conduct

1- Identification of infants with respiratory distress syndrome 2- Selection of patients by available method and based on inclusion and exclusion criteria 3- Grouping patients into two groups receiving intratracheal crossover surfactant and Braxorph randomly. 4- Comparison of data obtained in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Infants with respiratory distress disease 2- The result of pregnancy is equal and more than 25 weeks up to equal to 37 weeks 3- Admission to the study no later than 8 hours after birth 4. Requires fio2 more than 30%. Exclusion criteria: Severe asphyxia at birth 5 minutes less than 6 minutes 2- Diagnosis of congenital major abnormalities such as heart disease and severe life-threatening abnormalities 3 - Multiple anomalies 4 -Early malignant toxic sepsis 5- Rupture of embryonic membranes for more than 18 hours.

Intervention groups

Intervention group 1: (Braxorf) surfactant produced by Teximadaru company (with initial dose of 4 cc per kilogram of body weight, repeat each dose for 6 to 12 hours, if necessary, up to 4 doses intratracheally. Intervention group 2: Kurosorf (surfactant produced by Chiesi Italy) with an initial dose of 2.5 cc per kilogram of body weight, repeat the dose every 12 hours, if necessary, up to 4 doses in the endotracheal.

Main outcome variables

Length of hospital stay, need and need for mechanical ventilation, BPD, death and drug side effects

General information

Reason for update

According to the investigator's opinion, study design needs to change.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170427033661N2**
Registration date: **2020-12-16, 1399/09/26**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **1**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name
Alireza Jashnimotlagh
Name of organization / entity
Alborz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 26 3222 2021
Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of intratracheal administration of Braksurf with curosurf on outcomes of neonates with respiratory distress syndrome admitted in intensive care unit

Public title
Comparative study of the effect of intratracheal administration of Braksurf with curosurf on outcomes of neonates with respiratory distress syndrome admitted in intensive care unit of Kamali hospital in 2019-2020
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infants with respiratory distress Pregnancy equal to and more than 25 weeks to equal to 37 weeks Admission up to 8 hours after birth Requires fio2 over 30%
Exclusion criteria:
Severe asphyxia at birth Apgar 5 minutes less than 6 Diagnosis of congenital major abnormalities such as heart disease and severe life-threatening abnormalities Multiple anomalies Early malignant toxic sepsis Rupture of embryonic membranes for more than 18 hours
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using random blocks of non-matched size and Randomization .com site.
Blinding (investigator's opinion)
Single blinded
Blinding description
The infants participating in the study are blind to the medication they received.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Alborz University of Medical Science
Street address
Alborz University of Medical Science, Office Park, Taleghani Square, Azimieh
City
Karaj
Province
Alborz
Postal code
3149779453
Approval date
2020-11-22, 1399/09/02
Ethics committee reference number
IR.ABZUMS.REC.1399.210

Health conditions studied

1

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
Length of hospital stay
Timepoint
End of the study
Method of measurement
Patient documentation

Secondary outcomes

1

Description
Duration requires mechanical ventilation
Timepoint
Patient discharge
Method of measurement
Hospital documentations

2

Description
Blood PH
Timepoint
The first 24 and 48 hours of life
Method of measurement

Based on arterial or venous blood samples

3

Description
HCO3
Timepoint
The first 24 and 48 hours of life
Method of measurement
Based on arterial or venous blood samples

4

Description
Pco2
Timepoint
The first 24 and 48 hours of life
Method of measurement
Based on arterial or venous blood samples

5

Description
sepsis
Timepoint
حین مطالعه
Method of measurement
General malaise with tachypnea / hypotension / unstable vital signs / positive blood or csf culture

6

Description
IVH
Timepoint
End of study
Method of measurement
Occurrence of intraventricular hemorrhage

7

Description
BPD
Timepoint
End of study
Method of measurement
Occurrence of oxygen dependence after 28 days

8

Description
Pneumothorax
Timepoint
End of study
Method of measurement
Occurrence of pneumothorax after injection by radiography

9

Description
Vital signs
Timepoint
Every 4 hours during the first 72 hours of a baby's life
Method of measurement
Measurement of heart rate, respiration rate, blood pressure and temperature

10

Description
Death
Timepoint
End of study
Method of measurement
Infant death

11

Description
Drug side effects
Timepoint
End of study
Method of measurement
Based on examination and history

Intervention groups

1

Description
Intervention group: (Braxorf) Surfactant manufactured by Teximadaru Company (with an initial dose of 4 cc per kilogram of body weight, repeat each dose for 6 to 12 hours, if necessary, up to 4 doses in the trachea.
Category
Treatment - Drugs

2

Description
Intervention group: Kurosorf (surfactant produced by the Italian company Chiesi) with an initial dose of 2.5 cc per kilogram of body weight, repeat the dose every 12 hours if needed, up to 4 doses in the trachea.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان کمالی
Full name of responsible person
Dr Alireza jashni motlagh
Street address
Shohada Square, Kamali St., Kamali Educational and Medical Center
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3149779453

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Kamali@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz university of medical sience
Full name of responsible person
Alireza Jashni Motlagh
Street address
45 meters from Golshahr - Saffarian Alley - Deputy of Research and Technology
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3198764653
Phone
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Email
Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz university of medical sience
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
Alborz University of Medical Sciences
Full name of responsible person
Dr Alireza Jashni Motlagh
Position
Neonatal subspecialty
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Shohada Square, Kamali St, Kamali Educational and Medical Center
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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