

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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: Kurosurf (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)

##### Phone

+98 26 3222 2021

##### Email address

dr.jashnimotlagh@abzums.ac.ir

##### 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**

HCO<sub>3</sub>

**Timepoint**

The first 24 and 48 hours of life

**Method of measurement**

Based on arterial or venous blood samples

### 4

**Description**

Pco<sub>2</sub>

**Timepoint**

The first 24 and 48 hours of life

**Method of measurement**

Based on arterial or venous blood samples

### 5

**Description**

sepsis

**Timepoint**

حين 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

**City**

Karaj

**Province**

Alborz

**Postal code**

3149779453

**Phone**  
+98 26 3222 2021  
**Email**  
Kamali@abzums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Alborz university of medical science  
**Full name of responsible person**  
Alireza Jashni Motlagh  
**Street address**  
45 meters from Golshahr - Saffarian Alley - Deputy of  
Research and Technology  
**City**  
Karaj  
**Province**  
Alborz  
**Postal code**  
3198764653  
**Phone**  
+98 26 3464 3774  
**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 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**  
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  
**Street address**  
Shohada Square, Kamali St, Kamali Educational and  
Medical Center

**City**  
Karaj  
**Province**  
Alborz  
**Postal code**  
3149779453  
**Phone**  
+98 26 3222 2021  
**Email**  
dr.jashnimotlagh@abzums.ac.ir

## Person responsible for scientific 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  
**Street address**  
Shohada Square, Kamali St, Kamali Educational and  
Medical Center  
**City**  
Karaj  
**Province**  
Alborz  
**Postal code**  
3149779453  
**Phone**  
+98 26 3222 2021  
**Email**  
dr.jashnimotlagh@abzums.ac.ir

## Person responsible for updating data

#### 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  
**Street address**  
Shohada Square, Kamali St, Kamali Educational and  
Medical Center  
**City**  
Karaj  
**Province**  
Alborz  
**Postal code**  
3149779453  
**Phone**

+98 26 3222 2021

**Email**

dr.jashnimotlagh@abzums.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