

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Efficacy and Safety of Intra-Tracheal Administration of Beraksurf in Comparison with Survanta and Curosurf in Neonates with Respiratory Distress Syndrome: A Three-Arm Randomized Clinical Trial

Protocol summary

Study aim

Comparison of efficacy and short-term and long-term side effects of Beraksurf with Survanta and Curosurf in neonates with RDS

Design

A clinical trial of three arms without a control group with parallel groups, two-way blind, randomized, phase 3 on 102 patients, randomization based on double triple allele block method of Excel software

Settings and conduct

This dissertation was part of a three-center study conducted at Tehran University of Medical Sciences, Valiasr Hospital. After randomization, the first group consisted of 36 infants treated with Beraksurf, the second group consisted of 31 infants treated with Curosurf, and the third group consisted of 35 infants who received Survanta. Information about the Survanta group was collected from the medical records of eligible infants who had received Survanta in the previous year (2018) due to the lack of this surfactant in the market and restrictions on the import of this drug due to sanctions. Participants (infants) and researchers collecting data and analyzing data were blinded to the allocation of each infant to each group, and only the health care and physician were aware of this due to the different nature of the drugs.

Participants/Inclusion and exclusion criteria

Premature neonates with RDS

Intervention groups

A: Beraksurf B: Survanta C: Curosurf

Main outcome variables

Oxygen index (OI) and the duration of ventilation after administration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201213049705N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **retrospective**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Afsaneh Alomohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

2019-10-25, 1398/08/03

Actual recruitment end date

2020-05-09, 1399/02/20

Trial completion date

2020-07-14, 1399/04/24

Scientific title

Evaluation of the Efficacy and Safety of Intra-Tracheal

Administration of Beraksurf in Comparison with Survanta and Curosurf in Neonates with Respiratory Distress Syndrome: A Three-Arm Randomized Clinical Trial		Secondary Ids	empty
Public title	the Efficacy and Safety of Intra-Tracheal Administration of Beraksurf in Comparison with Survanta and Curosurf in Neonates with RDS	Ethics committees	<u>1</u>
Purpose	Treatment	Ethics committee	
Inclusion/Exclusion criteria		Name of ethics committee	Ethics Committee of Tehran University of Medical Sciences
Inclusion criteria:	Neonates with RDS Premature infants with ≥ 25 to 34 weeks of gestation Included during the first 8 hours of birth required more than 30% FIO ₂	Street address	Keshavarz Blvd.
Exclusion criteria:	severe asphyxia at birth with a 5th minute Apgar score of less than 6 severe congenital anomalies such as heart disease and life-threatening abnormalities Rupture of membranes for longer than 2-weeks Multiple anomalies septicemia, respiratory failure for reasons other than RDS	City	Tehran
Age	From 1 day old to 2 months old	Province	Tehran
Gender	Both	Postal code	1419733134
Phase	3	Approval date	2019-01-30, 1397/11/10
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	Ethics committee reference number	IR.TUMS.IKHC.REC.1397.302
Sample size	Target sample size: 90 Actual sample size reached: 102	Health conditions studied	<u>1</u>
Randomization (investigator's opinion)	Randomized	Description of health condition studied	Respiratory distress syndrome
Randomization description	Randomization was performed between the three groups using blocks of double triple allele random numbers (size 6); group A: Beraksurf, group B: Survanta, group C: Curosurf.	ICD-10 code	J00-J99
Blinding (investigator's opinion)	Double blinded	ICD-10 code description	Diseases of the respiratory system
Blinding description	Participants (infants) were unaware of the type of drug used, the physician prescribing the drug and observing the symptoms and side effects was aware of the type of intervention because that the form and nature of the drugs were different and it was not possible to unify them. The researchers who collected, reviewed, and analyzed the data were blinded to the type of interventions.	Primary outcomes	<u>1</u>
Placebo	Not used	Description	Percentage of infants with low oxygen index, which was considered to require more than 30% FIO ₂ .
Assignment	Parallel	Timepoint	monitoring the displayed amount on the ventilator's monitor every 4 hours for the first 72 hours and after that every 12 hours until the 28th day. Arterial blood gas (ABG) or venous blood gas (VBG) was taken every 4 to 6 hours in the first 24 hours and every 4 to 12 hours in the next 48 hours.
Other design features		Method of measurement	Ventilator device and taking venous and arterial blood and sending to emergency laboratory for ABG and VBG tests.
		Secondary outcomes	<u>1</u>
		Description	death
		Timepoint	

Every 2 to 4 hours for 28 days
Method of measurement
Checking the neonate's vital signs

2

Description
duration of the mechanical ventilation

Timepoint
every 4 hours

Method of measurement
Checking the oxygen index and oxygen saturation percentages of the ventilator and ABG and VBG tests

3

Description
Sepsis

Timepoint
every 2 to 4 hours

Method of measurement
General malaise with tachypnea / hypotension / symptom instability / plus positive blood culture or CSF.

4

Description
bronchopulmonary dysplasia (BPD)

Timepoint
every 4 hours

Method of measurement
Oxygen dependence after 28 days by checking the status of respiratory indices

Intervention groups

1

Description
Intervention group: Beraksurf group. In this group, Beraksurf ampoules made by Tekzima Daru Company (Iran) in a dose of 4cc/kg will be injected intratracheally. Injections can be injected every 6 to 12 hours and up to 4 doses if needed until the patient's FIO2 reaches 30%.

Category
Treatment - Drugs

2

Description
Intervention group: Survanta group. In this group, Survanta ampoule made by Chiesi company (Italy) with an initial dose of 2.5cc/kg will be injected intratracheally. If needed, repeated every 12 hours and a maximum of two doses of 1.25cc/kg can be injected until the patient's FIO2 reaches 30%.

Category
Treatment - Drugs

3

Description
Intervention group: Curosurf group. In this group,

Kurosurf ampoules made by Abbot Company (USA) with an initial dose of 4cc / kg will be injected intrachip. If needed, repeat every 6 to 12 hours and up to 4 doses of 4cc / kg can be injected until the patient's FIO2 reaches 30%.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr hospital, Imam Khomeini hospital complex

Full name of responsible person

Dr. Afsaneh Alimohammadi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Alimohammadi

Position

Neonatologist

Latest degree

Subspecialist

Other areas of specialty/work

Neonatology

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Position

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data related to patients' demographic information, primary and secondary outcomes, other than those mentioned in the article resulting from the project, will be provided to them if requested by the editor or reviewers of the journal in which the article was submitted. The data will be published if the journal's instructions make it mandatory to provide all additional data as a supplementary file.

When the data will become available and for how long

If it is needed as a supplementary file, at the same time as submitting the article and at the request of the journal for about two weeks

To whom data/document is available

The editor and editors of the magazine will be able to access it at the request and in case of compulsion as a

supplementary file, everyone will be able to access.

Under which criteria data/document could be used

In order to further investigate the journal team and answer any questions they may have, and if required, to provide it as a supplementary file, no data restrictions will be provided.

From where data/document is obtainable

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

The requesting persons while introducing themselves must explain why they are requesting access to the data in an e-mail. A signed form of data rights and copyright laws must be submitted. after reviewing the information request in consultation with other authors, the data will be available within two to three weeks.

Comments