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 Braksurf 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)
Phone
+98 21 6119 2240
Email address
afsanehahimohamadi788693@gmail.com

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

Public title
the Efficacy and Safety of Intra-Tracheal Administration of Beraksurf in Comparison with Survanta and Curosurf in Neonates with RDS

Purpose
Treatment

Inclusion/Exclusion criteria

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% FIO2

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

Age
From **1 day** old to **2 months** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **102**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

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.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1419733134

Approval date
2019-01-30, 1397/11/10

Ethics committee reference number
IR.TUMS.IKHC.REC.1397.302

Health conditions studied

1

Description of health condition studied
Respiratory distress syndrome

ICD-10 code
J00–J99

ICD-10 code description
Diseases of the respiratory system

Primary outcomes

1

Description
Percentage of infants with low oxygen index, which was considered to require more than 30% FIO2.

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.

Method of measurement
Ventilator device and taking venous and arterial blood and sending to emergency laboratory for ABG and VBG tests.

Secondary outcomes

1

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 intrateracheally. 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, Kurosorf 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

Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733134

Phone

+98 21 6119 2052

Email

afsanehalimohamadi788693@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. mohammad Ali Sahraian

Street address

Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733134

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

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
Street address
Kashavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733134
Phone
+98 21 6119 2052
Email
afsanehalimohamadi788693@gmail.com

Person responsible for scientific 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
Street address
Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733134
Phone
+98 21 6119 2052
Email
afsanehalimohamadi788693@gmail.com

Person responsible for updating data

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
Street address
Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733134
Phone
+98 21 6119 2052
Email
afsanehalimohamadi788693@gmail.com

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

Afsaneh Alimohammadi Address: 2nd floor, Vali-Asr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran, Iran. E-mail: afsanehalimohamadi788693@gmail.com Tel.: +98 2161192052

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