Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of efficacy & safety of intratracheal Beraksurf with Survanta and Curosurf in preterm newborns with Respiratory distress syndrome (RDS)

Protocol summary

Study aim
Comparison of efficacy & safety of intratracheal Beraksurf with Survanta and Curosurf in preterm newborns with Respiratory distress syndrome (RDS)

Design
A randomized clinical trial (using permuted block), single blinded, with parallel 3 groups, N= 30 patients (each group N= 90), Phase 4

Settings and conduct
This interventional study will conducted from Jan 2019 to June 2020. 90 preterm neonate with diagnosis of RDS admitted in PICU of Akbar Abadi Hospital Tehran were selected. Neonates are randomly assigned to three groups. In the first intervention group, intratracheal Beraksurf (produced by Tekzima, Iran) is given every 6-12 hours at a dose of 4 cc / kg until the Fio2 is less than 30%. In the second intervention group, intratracheal Survanta (produced by ABBOT, US) every 6-12 hours at a dose of at a dose of 4 cc / kg until the Fio2 is less than 30%. In the third intervention group, intratracheal Curosurf (produced by chiesi, Italy) every 6-12 hours at a dose of at a dose of 4 cc / kg until the Fio2 is less than 30%. in this study only neonates are blind.

Participants/Inclusion and exclusion criteria
Parents consent to participate study premature neonates with a gestational age of less than 34 weeks premature neonates with diagnosis of RDS and candidates for surfactant A maximum of 8 hours have elapsed since the birth

Intervention groups
No parents consent to participate study Newborns with congenital heart diseases and other life threatening congenital anomalies. Adverse drug effects

Main outcome variables
Improved outcomes in RDS (before intervention and after intervetion)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200529047594N1**
Registration date: **2020-06-08, 1399/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-08, 1399/03/19**
Update count: **0**

Registration date
2020-06-08, 1399/03/19

Registrant information

Name
Niknaz Kabiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-22, 1398/11/02

Expected recruitment end date
2020-06-22, 1399/04/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of efficacy & safety of intratracheal Beraksurf with Survanta and Curosurf in preterm newborns with Respiratory distress syndrome (RDS)

Public title
Comparison of efficacy & safety of Beraksurf with Survanta and Curosurf in preterm newborns with Respiratory distress syndrome (RDS)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Parents consent to participate study premature neonates with a gestational age of less than 34 weeks premature neonates with diagnosis of RDS and candidates for surfactant A maximum of 8 hours have elapsed since the birth

Exclusion criteria:
No parents consent to participate study Newborns with congenital heart diseases and other life threatening congenital anomalies. Adverse drug effects

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Newborns are assigned to three groups: bracsurf (group A), survanta (group B) and Curosurf (group c). There are six possible block sequences of block size 3. Possible combinations include ABC, ACB, BAC, BCA, CAB, CBA. Initially, one of the compounds is randomly selected, and 3 individuals are assigned to each block. This process is repeated many times to include the eligible sample size.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, samples of the research are blinded (parents know about the study drugs, but they will not be informed about grouping A, B & c).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemat Highway, Next to the Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-01-21, 1398/11/01

Ethics committee reference number
IR.IUMS.FMD.REC.1398.548

Health conditions studied

1

Description of health condition studied
Respiratory Distress Syndrome (RDS)

ICD-10 code
P22.0

ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
improved outcomes in RDS

Timepoint
Before intervention and after intervention

Method of measurement
the need for mechanical ventilation, Venous Blood Gas

2

Description
Mortality

Timepoint
During the hospital stay

Method of measurement
Dead / alive

3

Description
Drug-related complications

Timepoint
During the hospital stay

Method of measurement
Yes/No

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes premature neonates with RDS diagnosis. In this group, samples (n=30) received intratracheal Beraksurf (produced by Tekzima, Iran) at a dose of 4 cc / kg every 6-12 hours until the Fio2 is less than 30%.
Category
Treatment - Drugs

2

Description
Intervention group 2: Includes premature neonates with RDS diagnosis. In this group, samples (n=30) received intratracheal Survanta (produced by ABBOT, US) at a dose of 4 cc / kg every 6-12 hours until the Fio2 is less than 30%.
Category
Treatment - Drugs

3

Description
Intervention group 3: Includes premature neonates with RDS diagnosis. In this group, samples (n=30) received intratracheal Curosurf (produced by chiesi, Italy) at a dose of 4 cc / kg every 6-12 hours until the Fio2 is less than 30%.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar-Abadi Hospital
Full name of responsible person
Niknaz Kabiri
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Molavi Ave, Sjahid AkbarAbadi Hospital.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Niknaz Kabiri
Position
Resident
Latest degree
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Other areas of specialty/work
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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