

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 be conducted from Jan 2019 to June 2020. 90 preterm neonates 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 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 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 intervention)

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)

Phone

+98 21 2304 6253

Email address

kabiri.n@iums.ac.ir

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

Street address

Molavi Ave, Sjahid AkbarAbadi Hospital.

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1168743514

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abas Motevalian

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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

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Kalani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Resident

Latest degree

Subspecialist

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