

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the Efficacy and Side-effects of Two Surfactants (Beraksurf, and Bles) in the Treatment of Respiratory Distress Syndrome among Preterm infants

Protocol summary

Study aim

Comparing The effects of 2 type of Surfactant

Design

Clinical randomized trial with 2 Intervention groups design of 64 patients, two arm and single-blind

Settings and conduct

Preterm neonate in Kerman Afzalipour hospital with RDS at birth need to surfactant therapy randomized received one type of surfactant

Participants/Inclusion and exclusion criteria

Preterm neonate with RDS/ without congenital anomaly

Intervention groups

Intervention groups: Surfactant Bles and Surventa

Main outcome variables

Mortality; PDA; IVH; Pulmonary Hemorrhage; Pneumothorax; Sepsis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051148N1**

Registration date: **2021-07-11, 1400/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**

Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

mahdie eslamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3252 4893

Email address

m.eslamian84@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy and Side-effects of Two Surfactants (Beraksurf, and Bles) in the Treatment of Respiratory Distress Syndrome among Preterm infants

Public title

Compare two kinds of Surfactant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm neonate Respiratory distress syndrome

Exclusion criteria:

Congenital cardiac anomaly Congenital gastrointestinal anomaly Congenital urological anomaly Chromosomal disorder

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the analyzer, the data input form designed according to coding without recording the type of drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Afzalipur hospital, next to Shahid Bahonar University, Imam Khomeyny high way

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۹۱۱

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.KMU.AH.REC.1400.012

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrom

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Improvement Respiratory distress syndrom

Timepoint

From beginning, Daily

Method of measurement

Physical examination

2

Description

Mortality

Timepoint

From birthing continuous to end of treatment

Method of measurement

Vital sign checking

3

Description

Patent dactus arteriosus

Timepoint

From birthing intermittent echo cardiography

Method of measurement

Echo cardiography

4

Description

Intra ventricular hemorrhage

Timepoint

From birthing intermittent brain sonography

Method of measurement

Brain sonography

5

Description

pulmonary hemorrhage

Timepoint

Daily

Method of measurement

Physical examination

6

Description

Pneumothorax

Timepoint

Daily

Method of measurement

Physical examination and chest x-ray

7

Description

Sepsis

Timepoint

From birthing intermittent

Method of measurement

Blood culture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Intratecal administration of Surfactant kind Bles, Immediately after birth, up to 72 hours later, by clinical examination or by X-ray with the diagnosis of acute respiratory distress, the first dose of the drug is injected, repeated 6 hours after the X-ray injection, and if necessary, re-injection up to a maximum Up to three times, the dose of the drug in each injection is 135 mg per kilogram of baby weight, equivalent to 5 cc per kilogram of baby weight, the active ingredient of the drug is Thostidil colin, and this drug is made in Canada.

Category

Treatment - Drugs

2

Description

Intervention group 2: Intratecal administration of Surfactant kind Beraksorf, Immediately after birth, up to 72 hours later, by clinical examination or by X-ray with the diagnosis of acute respiratory distress, the first dose of the drug is injected, repeated 6 hours after the X-ray injection, and if necessary, re-injection up to a maximum Up to three times, the dose of the drug in each injection is 100 mg per kilogram of baby weight, equivalent to 4 cc per kilogram of baby weight, the active ingredient of the drug is Thostidil colin, and this drug is made in IRAN by Tekzima co.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Kerman hospital

Full name of responsible person

Mahdie Eslamian

Street address

Afzalipour hospital, Next to Shahid Bahonar University, Imam Khomayni high way

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info@ah.kmu.ac.ir

Web page address

<http://ah.kmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpur Afshar

Street address

Afzalipour Hospital, Next to Shahid bahonar university, Imam Khomayni High way

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mahdie Eslamian

Position

Flowship of Neonatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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