

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

clinical trial for comparing impact of Bles versus Curosurf in management of respiratory distress syndrome in preterm neonates hospitalized in neonatal intensive care unit

Protocol summary

Summary

Purpose: comparing impact of Bles versus Curosurf on management of respiratory distress syndrome among preterm neonates hospitalized neonatal intensive care unit. Design: 240 preterm infants who were hospitalized in Neonatal Intensive Care Unit, will participate in the present trial. Included infants had less than 34 weeks' gestational age and confirmed respiratory distress syndrome. Setting and conduct: trial participants will be randomly allocated to two parallel trial groups. In one trial group, neonates will receive Curosurf 2.5 cc/kg and in another group, neonates will receive Bles 5 cc/kg. Participants: Inclusion criteria are preterm infants with less than 34 weeks' gestational age and confirmed respiratory distress syndrome. among included infant, those who have sepsis diagnosis, congenital cardiac disorders, pulmonary hemorrhage and congenital pneumonia will excluded from the trial. Intervention: Curosurf with 2.5 cc/kg dosage in one group and Bles with 5 cc/kg dosage in another group. Outcome: Oxygen index, ventilator using time, nCPAP using time, hospitalization time, side effects of intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021418994N3**
Registration date: **2017-04-07, 1396/01/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-07, 1396/01/18

Registrant information

Name

Amir Bahrami-Ahmadi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of medical Sciences

Expected recruitment start date

2016-06-22, 1395/04/02

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical trial for comparing impact of Bles versus Curosurf in management of respiratory distress syndrome in preterm neonates hospitalized in neonatal intensive care unit

Public title

Comapring impact of Bles versus Curosurf in respiratory distress of preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: less than 34 weeks gestational age;

Confirmed Respiratory Distress Syndrome Exclusion
Criteria: Confirmed Sepsis; Congenital heart diseases;
Pulmonary hemorrhage; Congenital Pneumonia

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization according Balanced Blocked

Randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman Kerman University of
Medical Sciences

Street address

Ebnesina Street- Jahad Blv-Tahmasb Abad

City

Kerman

Postal code

Approval date

2017-02-13, 1395/11/25

Ethics committee reference number

IR.KMU.REC.1395.839

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

P.22.0

ICD-10 code description

Hyaline membrane disease

Primary outcomes

1

Description

Oxygenic Index

Timepoint

Before and 12 hours after intervention

Method of measurement

According ABG and ventilator indices

2

Description

Ventilation period

Timepoint

Before and 12 hours after intervention

Method of measurement

Neonates medical records

3

Description

nCPAP period

Timepoint

before and 12 hours after Intervention

Method of measurement

Neonates medical records

4

Description

Hospitalization time

Timepoint

After Intervention

Method of measurement

Neonates medical records

Secondary outcomes

1

Description

Mortality rate

Timepoint

Before and 12 hours after intervention

Method of measurement

medical folder of neonates

Intervention groups

1

Description

Advising Coursurf with 2.5 cc/kg slowly via neonatal
trachea with vital sign control and cardiopulmonary
monitoring

Category

Treatment - Drugs

2

Description

Advising Bles 5 cc/kg rapidly via neonatal trachea with vital sign control and cardiopulmonary monitoring

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Dr Zeinab Kheradmand

Street address

Afzalipour Hospital, Afzalipour Campus, Imam Highway, Kerman, Iran

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Vice Chancellor of Kerman University of Medical Sciences, Ebne sina street, Jahad Blvd, Tahmasabad crossroad, Kerman, Iran

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor of Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Zeinab Kheradmand

Position

Pediatric specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Professor of Pediatric ward

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty