Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Iran (Islamic Republic of)

Phone

+98 21 8862 2682

Email address

bahrami.a@iums.ac.ir

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 Scieneces

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 Dystress 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 Cursourf 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
Street address
Vice chancellor Kerman University of Medical Science, Ebnesina Street, Jahad Blvd, Tahmasabad crossroad, Kerman
City
Kerman
Postal code
Phone
+98 34 3132 5700
Fax
Email
vcr@kmu.ac.ir
Web page address
vcrt.kmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Pedram Niknafs
Position
Professor of Pediatric ward
Other areas of specialty/work
Street address
Vice-Chancellor of Kerman University of Medical Sciences, Ebnesina street, Tahmasbabad Crossroad, Kerman
City
Kerman
Postal code
Phone
+98 34 3132 5700
Fax
Email
kmu_research@yhoo.com
Web page address
vcrt.kmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Amir Bahrami-Ahmadi
Position
Other areas of specialty/work
Street address
Vice Chancellor of Kerman University of Medical Sciences, EbneSina Street, Tahmasabbad Crossroad, Kerman
City
Kerman

Postal code

Phone

+98 34 3132 5700

Fax

Email

Web page address

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