

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the efficacy of two natural surfactants, Curosurf® and BLES®, in treatment of respiratory distress syndrome in preterm neonates

Protocol summary

Study aim

The aim of this study is comparing the effects of Curosurf and BLES surfactants in the treatment of neonatal respiratory distress syndrome (RDS).

Design

Study design: Randomized double-blind clinical trial. Patients will be assigned into two groups to receive either Curosurf surfactant (n=80) or BLES surfactant (n=80).

Settings and conduct

Among patients with RDS admitted to NICU of Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences, 160 patients will be selected according to inclusion and exclusion criteria. The medical team, parents, and outcome assessor are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates with RDS, gestational age of 32 weeks or less. Exclusion criteria: Congenital anomalies, Apgar score less than 4 at 5 minutes, meconium aspiration syndrome, prolonged premature rupture of membrane, parents declined to participate.

Intervention groups

Intervention group 1: 200 mg/kg intratracheal Curosurf surfactant (Chiesi Farmaceutici, Parma, Italy).
Intervention group 2: 135 mg/kg intratracheal BLES surfactant (BLES Biochemicals Inc., Ontario, Canada).

Main outcome variables

Outcomes: the number of surfactant injection (primary outcome) and length of oxygen dependency, duration of hospital stay, and complications of prematurity (secondary outcomes) will be evaluated.

General information

Reason for update

Updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N54**

Registration date: **2019-03-30, 1398/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **2**

Registration date

2019-03-30, 1398/01/10

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-01-07, 1397/10/17

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2021-11-07, 1400/08/16

Trial completion date

2022-02-05, 1400/11/16

Scientific title

Comparing the efficacy of two natural surfactants, Curosurf® and BLES®, in treatment of respiratory distress syndrome in preterm neonates

Public title

Comparing Curosurf® and BLES® in treatment of respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Neonates with respiratory distress syndrome (RDS) gestational age of 32 weeks or less.

Exclusion criteria:

Exclusion criteria: congenital anomalies. Apgar score less than 4 at 5 minutes. neonates with meconium aspiration syndrome. prolonged premature rupture of membrane. parents declined to participate.

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Neonates will be randomly assigned into two groups. A randomization list will be generated from 1 to 160 by SPSS software (version 16) and neonates were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Allocation concealment will be done by having procedure indicator cards inside a set of opaque sealed envelopes. The medical team, parents, and outcome assessor are unaware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical

Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2018-04-09, 1397/01/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.003

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22

ICD-10 code description

Respiratory distress of newborn

Primary outcomes

1

Description

The number of surfactant injection

Timepoint

After the intervention

Method of measurement

Checklist

Secondary outcomes

1

Description

Length of oxygen dependency

Timepoint

After the intervention

Method of measurement

Checklist

2

Description

Duration of hospital stay.

Timepoint

After the intervention

Method of measurement

Checklist

3

Description

Complications of prematurity

Timepoint

After the intervention

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group 1: 200 mg/kg intratracheal Curosurf surfactant (Chiesi Farmaceutici, Parma, Italy).

Category

Treatment - Drugs

2

Description

Intervention group 2: 135 mg/kg intratracheal BLES surfactant (BLES Biochemicals Inc., Ontario, Canada).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Dr. Mohammad Reza Sharif

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Banafsheh

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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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Sharif

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Pediatrics

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Isfahan

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