

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy and safety of two natural surfactants, Curosurf and Surfacta in treatment of respiratory distress syndrome: A randomized clinical trial

Protocol summary

Summary

This study aimed to compare the effectiveness and safety of Curosurf and Surfacta in treatment of respiratory distress syndrome (RDS). One hundred and twelve neonates were born with RDS diagnosis in Najmeh and Baqiyatallah hospitals in 2014 were randomly selected. Other inclusion criteria were weight of 750 to 1750 gr; gestational age less than 35 weeks; O2 saturation 85% to 96%; signed informed consent by parents, and age $\leq$ 6 hours at the time of randomization. RDS diagnosis was based on clinical picture of infant with the onset of progressive respiratory failure shortly after birth, in conjunction with a characteristic chest radiograph. Neonates with congenital heart diseases and other life threatening anomalies, respiratory failure due to other causes except RDS, 5 minute Apgar score $\leq$ 3, and proven fetal lung maturity profile from amniocentesis were excluded from study. Neonates were randomly assigned into two groups. Randomization was stratified by birth weight with two birth weight strata (750 to 1250 gr and 1250 to 1750 gr). After intubation the groups one and two infants were received 100 mg/kg Curosurf or Surfacta as soon as possible after randomization. The efficacy and RDS complications were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071017413N12**
Registration date: **2015-09-01, 1394/06/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Deputy of Research

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of two natural surfactants, Curosurf and Surfacta in treatment of respiratory distress syndrome: A randomized clinical trial

Public title

Comparison of efficacy and safety of two natural surfactants, Curosurf and Surfacta in treatment of

neonatal respiratory distress syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Neonates were born with RDS diagnosis in Najmieh and Baqiyatallah hospitals; weight of 750 to 1750 gr; gestational age less than 35 weeks; O2 saturation 85% to 96%; signed informed consent by parents; and age $\leq$ 6 hours at the time of randomization. Exclusion criteria: Congenital heart diseases and other life threatening congenital anomalies; respiratory failure due to other causes, 5 minute Apgar score $\leq$ 3; proven fetal lung maturity profile from amniocentesis; prior treatment with exogenous surfactant; prolonged ($\geq$ 3 weeks) rupture of membranes; untreated hypotension or hypoglycemia; use of high-frequency ventilation prior to first dose of surfactant; and severe grades of intra-ventricular hemorrhage (grades III or IV) prior to surfactant.

Age
To 1 day old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 112

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences Ethics Committee

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Approval date

2015-05-10, 1394/02/20

Ethics committee reference number

IR.BMSU.REC.1394.107

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Needing second surfactant dose

Timepoint

12 to 24 hours after the first surfactant dose

Method of measurement

Yes / No

2

Description

Hospital stay

Timepoint

At the time of discharge

Method of measurement

Days

3

Description

Mortality

Timepoint

During the hospital stay

Method of measurement

Dead / alive

4

Description

Needing nasal continuous positive airway pressure

Timepoint

During the hospital stay

Method of measurement

Yes / No

5

Description

Needing endotracheal tube

Timepoint

During the hospital stay

Method of measurement

Yes / No

6

Description

RDS-related complications

Timepoint

During the hospital stay

Method of measurement

Yes / No

Secondary outcomes

empty

Intervention groups

1

Description

After intubation the group one infants were received 100 mg/kg Curosurf as soon as possible after randomization.

Category

Treatment - Drugs

2

Description

After intubation the group two infants were received 100 mg/kg Surfactant as soon as possible after randomization.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Sobhan Amin

Street address

Baqiyatallah Hospital, Sheikh Bahaei St. Mollasadra St. Vanak Sq. Tehran, I.R.Iran

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2

Recruitment center

Name of recruitment center

Najmieh Hospital

Full name of responsible person

Bitra Najafian

Street address

Baqiyatallah Hospital, Sheikh Bahaei St. Mollasadra St. Vanak Sq. Tehran, I.R.Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences, Deputy of Research

Full name of responsible person

Gholam Hossein Alishiri

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Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

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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

Baqiyatallah University of Medical Sciences, Deputy of Research

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

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran

Full name of responsible person

Hamidreza Karimi-Sari

Position

General practitioner / Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

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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