

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect and outcome of Surfactant (CUROSURF) with doses 100 & 200 mg/kg in neonates with respiratory distress syndrome

Protocol summary

Study aim

Evaluation of hospitalization period and duration of supplemental oxygen requirement and possible complications (pneumonia, intracerebral hemorrhage, intrapulmonary hemorrhage, necrotizing enterocolitis) and duration of oral feeding and re-need of surfactant injection after initial injection in two groups receiving surfactant With two different doses.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients

Settings and conduct

Neonatal Intensive Care Unit (NICU) of Valiasr Hospital in Birjand, in the field of treatment and the mentioned infants are randomly divided into two groups and each group is prescribed a different dose of endotracheal surfactant. The patient group and the data evaluator and data analyst group do not know the dose given in the two groups.

Participants/Inclusion and exclusion criteria

All infants with acute respiratory distress syndrome(RDS) need medical treatment / unless they have undergone cardiac resuscitation at birth

Intervention groups

Neonates admitted to the neonatal intensive care unit(NICU) with a diagnosis of acute respiratory distress syndrome(RDS) are randomly divided into two groups, and each group receives a prescribed dose of surfactant (100 mg/kg or 200 mg/kg) for that group.

Main outcome variables

Duration of hospitalization, complications of treatment, need for mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210102049921N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **prospective**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

Reza Poorhoseiny

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3162 2001

Email address

reza.poorhoseiny52@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-06, 1400/03/16

Expected recruitment end date

2021-09-07, 1400/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect and outcome of Surfactant (CUROSURF) with doses 100 & 200 mg/kg in neonates with respiratory distress syndrome

Public title

Effect different doses of Surfactant (CUROSURF)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with respiratory distress syndrome Requires treatment with Surfactant

Exclusion criteria:

Cardiopulmonary resuscitation during labour

Age

To 2 days old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Lack of information of the given drug dose in patients and data analyst and outcome assessor

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghafari Blvd.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2020-12-21, 1399/10/01

Ethics committee reference number

IR.BUMS.REC.1399.421

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn (RDS)

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Daily

Method of measurement

Calendar

2

Description

Complications of treatment

Timepoint

Duration of hospitalization

Method of measurement

Chest-X-ray and clinical observation

3

Description

Requires a variety of auxiliary ventilation

Timepoint

every hour

Method of measurement

Digital clock

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intratracheal injection of surfactant under the brand name Curosurf at a dose of 100 mg/kg made by Chiesi Farmaceutici factory(Italy)

Category

Treatment - Drugs

2

Description

Intervention group: Intratracheal injection of surfactant under the brand name Curosurf at a dose of 200 mg/kg made by Chiesi Farmaceutici factory(Italy)

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-asr

Full name of responsible person

Mahmoudirad Alireza

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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research@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Reza Poorhoseiny

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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