Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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

Treatment - Drugs

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
Academic

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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Person responsible for updating data

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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