Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of therapeutic effects of Iranian surfactant (Beraksurf) with Cursorf in premature infants with respiratory distress admitted to the neonatal intensive care unit of Hafez and Namazi hospitals in Shiraz in 1400

Protocol summary

Study aim
Determining the therapeutic effects of surfactant made in Iran (Beraksurf) compared to cursorf in treatment of neonates with respiratory syndrome admitted in neonatal intensive care unit in Hafez and Namazi hospital

Design
A randomized clinical trial with parallel two intervention groups (1 and 2), single blinded, randomized, N= 100 patients (each group N= 50) and phase 2. Block randomization will be used for randomization.

Settings and conduct
This research includes preterm neonates, admitted to Hafez or Namazi hospital who need receiving surfactant. Then beraksurf or cursorf is given. Blinding in this research is single-blind and parents do not know their neonate is in which group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age less than 37 weeks, the clinical or radiologic signs of respiratory distress syndrome, need Fio2 more than 30% in the first 6hour of life to keep saturation 92-95%. Exclusion criteria: congenital disease or anomalies, receiving two types of surfactant, neonates who need an operation, neonates with congenital heart or lung disease, or abdominal pathology.

Intervention groups
The first group consists of neonates receiving Beraksurf and the second group of neonates receiving Cursorf due to respiratory distress syndrome.

Main outcome variables
Need a ventilator; O2 saturation rate; Sepsis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120126008827N3**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
Khadijeh Sadat Najib

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 71 1647 4298

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effects of Iranian surfactant (Beraksurf) with Cursorf in premature infants with respiratory distress admitted to the neonatal intensive care unit of Hafez and Namazi hospitals in Shiraz in 1400

Public title
Evaluation of the effect of Beraksurf and Cursorf in patients with respiratory distress

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age < 37 weeks Radiologic and clinical diagnosis during first 6 hours, Need to Fio2>30% for keeping o2 saturation 92-95% that measured by pulse oximetry

Exclusion criteria:
Patients with congenital disease and anomalies Receiving two types of surfactant due to lack or shortage of the drug Patients need operation Neonates with congenital heart or lung disease or abdominal pathology

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
En In this study, we will use the limited randomization method of block randomization, which is used to balance the number of participants in each study group. The size of the blocks is equal, and we will have 50 participants in each group. For block randomization, the size of the blocks is considered to be five. According to the sample size, 20 blocks will be selected based on a table of random numbers. The individuals are assigned to groups based on the position of the blocks. Random allocation concealment will be done using randomly sealed opaque envelopes. The random allocation sequence was computer-generated (Kendall and Smith's Random Numbers Table) by a statistician who was not a part of the research team. A random number table is a series of digits (0 to 9) arranged randomly in rows and columns, as demonstrated in the small sample below. The table usually contains 5-digit numbers, arranged in rows and columns, for ease of reading. The random allocation sequence was concealed in sealed opaque envelops until the participants were assigned into two groups participants were assigned into two groups

Blinding (investigator's opinion)
Single blinded

Blinding description
The blinding method in this study will be single-blind. The single-blind is used to reduce bias related to the intervention and evaluate the consequences. In this study, samples of the research are blinded (parents know about the study drugs, but they will not be informed about grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand street, Shiraz University of Medical Sciences, Shiraz

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2021-10-30, 1400/08/08

Ethics committee reference number
IR.SUMS.REC.1400.569

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
treatment of respiratory distress syndrome

Timepoint
evaluate respiratory condition of neonates at birth and 2, 6,12,18,24,36,48 and 72 hour after birth

Method of measurement
Beraksurf case report form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, 50 neonates with RDS diagnosis will receive intratracheal Beraksurf (produced by Tekzima, Iran) at a dose of 2.5 cc/ kg (200 mg/kg) every 6-12 hours until the Fio2 is less than 30%. For subsequent doses,100 mg/kg will be given up to three doses every 6 hours if needed.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, 50 neonates with RDS diagnosis will receive intratracheal Curosurf (produced by chiesi, Italy) at a dose of 4 cc/kg (200 mg/kg) every 6-12 hours until the Fio2 is less than 30%. For subsequent doses,100 mg/kg will be given up to three doses every 6 hours if needed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazee hospital
Full name of responsible person
Khadijeh Sadat Najib
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2

Recruitment center
Name of recruitment center
Hafez hospital
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mahtab Memarpour
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Khadijeh Sadat Najib
Position
Associate Professor
Latest degree
Subspecialist
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Neonatal
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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