# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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)

**Phone**
+98 71 1647 4298

**Email address**
nzahrasan@yahoo.com

**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
**Street address**
Nemazee square, Shiraz , Iran
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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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Mahtab Memarpour
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Shiraz University of Medical Sciences, Zand steert, Shiraz, 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**
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
**Other areas of specialty/work**
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