Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

A comparative study of the effect of Bractant and Corosurf on the duration of oxygen requirement in premature babies with respiratory distress syndrome with a gestational age of less than 32 weeks

Protocol summary

Study aim

A comparative study of the effect of Bractant and Corosurf on the duration of oxygen requirement in premature babies with respiratory distress syndrome

Design

This is a randomized, single-blinded clinical trial with a parallel design. This randomized study will be conducted on 58 premature babies with respiratory distress. A random block is used for randomization and the participants are assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah, is a single-blinded study. Surfactant injection at a dose of 100 mg/kg will be done through intrapulmonary intubation under sterile conditions and as instillation into the tube, and after instilling the surfactant, the baby will be ventilated and the tracheal tube will be removed and the baby will be treated with NCPAP or HFNC (INSURE).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature babies less than 32 weeks with respiratory distress syndrome; Infants who need surfactant Exclusion criteria: Existence of other respiratory diseases other than respiratory distress syndrome; Congenital heart abnormalities; A history of resuscitation at birth with severe metabolic vasculitis

Intervention groups

In the first intervention group, in the first 12 hours after birth, they will receive the manufactured Berketant surfactant (manufactured byTekzima, Iran), an 8cc vial prepared from pig lungs. The second intervention group will receive Corosurf surfactant (manufactured by Cheisi, Italy) in a 3 cc vial prepared from pig lungs in the first 12 hours after birth.

Main outcome variables

Duration of NICU stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N210**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**
Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative study of the effect of Bractant and Corosurf on the duration of oxygen requirement in premature babies with respiratory distress syndrome with a gestational age of less than 32 weeks

Public title
A comparative study of the effect of Bractant and Corosurf on the duration of oxygen requirement in premature babies with respiratory distress syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Premature babies less than 32 weeks with respiratory distress syndrome Infants who need surfactant
Exclusion criteria:
Existence of other respiratory diseases other than respiratory distress syndrome Congenital heart abnormalities A history of resuscitation at birth with severe metabolic vasculitis
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.
Blinding (investigator's opinion)
Single blinded
Blinding description
Medications can only be identified by the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study. The charge of injecting medications will not know about the assignment of individuals to groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2023-05-13, 1402/02/23
Ethics committee reference number
IR.KUMS.MED.REC.1402.061

Health conditions studied

1

Description of health condition studied
Distress syndrome of neonates
ICD-10 code
P22.0
ICD-10 code description
Respiratory distress syndrome of newborn

Primary outcomes

1

Description
Duration of NICU stay
Timepoint
End of study
Method of measurement
Based on the hospitalization record

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, in the first 12 hours after

birth, they will receive the manufactured Berketant surfactant (manufactured byTekzima, Iran), an 8cc vial prepared from pig lungs

Category

Treatment - Drugs

2

Description

The second intervention group will receive Corosurf surfactant (manufactured by Cheisi, Italy) in a 3 cc vial prepared from pig lungs in the first 12 hours after birth.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Maryam Reza Beigi

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

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6715847141

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+98 83 3427 6306

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maryamrezabeigi1358@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Cyrus Jalili

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Maryam Reza Beigi

Position
Resident of Pediatric

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Noushin Miladi

Position
Member of the academic staff of Kermanshah University of Medical Sciences

Latest degree
Specialist

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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available