Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of intra tracheal injection of budesonide with surfactant and surfactant alone in prevention of Bronchopulmonary Dysplasia in preterm infant under ۳۰ week with Respiratory Distress Syndrome A Randomized Cilinical Trial

Protocol summary

Study aim
Determination of the effect of budesonide intratracheal injection in the prevention of bronchopulmonary dysplasia in premature infants with a birth age of less than 30 weeks of gestation and respiratory distress syndrome

Design
A clinical trial with a control group

Settings and conduct
Kamali Hospital

Participants/Inclusion and exclusion criteria
Premature infants less than 30 weeks of age with respiratory distress syndrome

Intervention groups
Preterm infants who meet the conditions for entering the study are included in the study as available sampling and based on the list Randomization falls into one of the following two groups: mg/kg intervention in the first group including: intratracheal injection of surfactant 200 and followed by mg/kg and surfactant 200 budesonide 0.25 mg/kg in the second intervention group including intratracheal injection Budesonide 0.25 mg/kg (0.5 ml/kg) along with 100 mg/kg (1.25 ml/kg if needed)

Main outcome variables
Examination in terms of oxygen dependence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221016056205N1**
Registration date: **2023-05-15, 1402/02/25**
Registration timing: **registered_while_recruiting**
Last update: **2023-05-15, 1402/02/25**
Update count: **0**

Registration date
2023-05-15, 1402/02/25

Registrant information

Name
Sima Kianpisheh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of intra tracheal injection of budesonide with surfactant and surfactant alone in prevention of Bronchopulmonary Dysplasia in preterm infant under ۳۰ week with Respiratory Distress Syndrome A Randomized Cilinical Trial

Public title

Comparison of the effect of intra tracheal injection of budesonide with surfactant and surfactant alone in prevention of Bronchopulmonary Dysplasia in preterm infant under ۳۰ week with Respiratory Distress Syndrome A Randomized Cilinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All preterm babies with birth age less than 30 weeks provided they have respiratory distress syndrome (RDS) There is evidence of RDS in chest X-ray and ABG and they are candidates to receive surfactant Babies born at the hip less than 24 weeks of pregnancy - with a birth weight of less than 400 grams - the presence of congenital cardiopulmonary disease - conditions for not entering the study

Exclusion criteria:

A baby born less than 24 weeks old A baby with a birth weight of less than 400 grams A baby with a fatal congenital abnormality or disorder Presence of cardiopulmonary diseases

Age

From **6 months** old to **7 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: using block randomization with unequal block sizes (4 Two groups of comparison and intervention are interpreted. Confounding Control Method: Randomization of Allocation. Control in the analysis phase is different from statistical models. : Random allocation and concealment and blinding Hidden Privatization: By specifying unequal block sizes, the allocation sequence will be hidden. Pre-randomization list by web-provided software by the co-researcher who is in the interpretation process (https://www.sealedenvelope.com/simple-randomiser/v1/lists) He is not involved in preparing and only this researcher will have access to this list. At the time of identification of the qualified patient, the allocation group will be announced by him based on the prepared list. Blinding: The researcher evaluating the outcome of the specialized group of samples is known According to the fact that the patient is a baby and the parents will also perform the treatment without knowledge. The review of the final results of the study will be done by a doctor who was unaware of the type of intervention. For statistical analysis, a statistical expert is used who is not informed about how people are assigned to groups. Concealment Method Privatization Method: The problem allocation list is only available to the secretary of the department. In order to conceal the randomization process, the sequence of treatment is written on the cards in order, then the cards are placed in sealed envelopes. Each envelope has a random 10-digit code without order and identification of the corresponding patient number, and the only design of the methodologist will be the corresponding code. Because the doctor declares the eligibility of a patient, the secretary provides the envelope to the doctor and the desired treatment is carried out according to the specific type mentioned in the envelope. Preterm infants who meet the conditions for entering the study in the form of available sampling and are placed in one of the following two groups based on the randomization list: mg/kg intervention in the first group including: intratracheal injection of surfactant 200 and followed by . mg/kg and surfactant 200 budesonide 0.25 mg/kg in the second intervention group including intratracheal injection. kg if needed Sampling Type: Available. Randomization method: Using block randomization with unequal block sizes (4-6-8), the samples are assigned to one of the comparison and intervention groups. Confounding Control Method: Randomization of Allocation. Control in the analysis phase is different from statistical models.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

thics committee of Alborz University of Medical Sciences

Street address

Azimiyeh

City

Karaj

Province

Alborz

Postal code

1463614636

Approval date

2022-09-24, 1401/07/02

Ethics committee reference number

IR.ABZUMS.REC.1401.181

Health conditions studied

1

Description of health condition studied

Bronchopulmonary dysplasia

ICD-10 code
P27.1
ICD-10 code description
Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description
Severity of BPD: BPD will be divided into three groups in terms of severity: mild, which means that they do not need oxygen at the age of 36 weeks of pregnancy, and moderate, which means that they need less than 30% of oxygen in the 36th week of pregnancy. Severe need for 30% oxygen with or without positive pressure ventilation or continuous positive pressure at 36 weeks of gestation
Timepoint
After 28 days
Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Preterm infants who meet the conditions for entering the study are included in the study as available samples and are placed in one of the following two groups based on listrandomization: mg/kg intervention in the first group includes: intratracheal injection of surfactant 200 mg/kg
Category
Prevention

2

Description
Control group: Control group: under sterile conditions, surfactant is prepared in a syringe for the control group, and for the intervention group: surfactant and budesonide are mixed in a syringe and gently shaken to obtain a uniform solution before injection. Medicines are injected intratracheally. In case of surfactant or with budesonide, it can be repeated every 8 hours until a maximum of 6 doses have been received. FiO2 < 0.3, extubation when patients are hospitalized and not discharged, patients are visited daily, in the morning by the neonatologist, if they are discharged, they will be visited again after 72 hours.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Sima Kianpishe
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Raziyeh Lotfi
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Sima Kianpishe
Position
Resident of Pediatric
Latest degree
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Other areas of specialty/work
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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