

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Budesonide plus Surfactant in prevention of chronic lung disease in premature infants with gestational age less than 30 weeks

Protocol summary

Study aim

The effect of adding budesonide to surfactant on prevention of chronic pulmonary disease in premature infants less than 30 weeks

Design

A three phase clinical trial with one intervention group and one control group, in parallel groups, not blind, simple randomized, with coded card selection and with sample size of 190

Settings and conduct

In this study, a single-blind randomized controlled clinical trial. A total of 190 preterm infants less than 30 weeks of age (95 patients in each group) were selected as the study population from the NICU ward of Alzahra and Shahid Beheshti Hospitals in Isfahan and the effect of addition of budesonide to lung-injected surfactant Surfactants alone are being studied to reduce the risk of chronic lung disease (CLD).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants with pre-existing GA <30 weeks admitted to the NICU; Receives some kind of non-invasive respiratory support including CPAP and physician decides to prescribe surfactant; Exclusion criteria: Major congenital anomalies affecting neonatal respiration (severe pulmonary hypoplasia, congenital lung abnormality, congenital airway obstruction); Asphyxia; Gastrointestinal anomalies that cause the baby to be transferred to another center; Sepsis before starting the study; Cyanotic heart disease

Intervention groups

Neonates are randomly divided into two groups of surfactant (S) and surfactant + budesonide (B) combination.

Main outcome variables

The time required for mechanical ventilation; The period of time of no need for non-invasive ventilation; Duration of hospital stay; The period of time of Surfactant injections, The condition of chronic lung disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N38**

Registration date: **2020-05-08, 1399/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**

Update count: **0**

Registration date

2020-05-08, 1399/02/19

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-01-16, 1399/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Budesonide plus Surfactant in prevention of chronic lung disease in premature infants with gestational age less than 30 weeks

Public title

Effect of Budesonide with Surfactant on the prevention of chronic lung disease in premature infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with pre-existing GA <30 weeks admitted to the NICU Receives some kind of non-invasive respiratory support including CPAP and physician decides to prescribe surfactant

Exclusion criteria:

Major congenital anomalies affecting neonatal respiration (severe pulmonary hypoplasia, congenital lung abnormality, congenital airway obstruction) Asphyxia Gastrointestinal anomalies that cause the baby to be transferred to another center Sepsis before starting the study Cyanotic heart disease

Age

To **7 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **190**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the study, simple randomization with individual unit is used, so that patients randomly select one of the cards containing the codes A or B so they enter one of the two treatment groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

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Isfahan

Postal code

7346181746

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.MUI.MED.REC.1398.507

Health conditions studied

1

Description of health condition studied

Chronic lung disease

ICD-10 code

P27.8

ICD-10 code description

Other chronic respiratory diseases originating in the perinatal period

Primary outcomes

1

Description

The time required for mechanical ventilation

Timepoint

4 to 6 weeks after birth

Method of measurement

Check list

2

Description

The period of time of no need for non-invasive ventilation

Timepoint

4 to 6 weeks after birth

Method of measurement

Check list

3

Description

Duration of hospital stay

Timepoint

4 to 6 weeks after birth

Method of measurement

Check list

4

Description

The period of time of surfactant injections

Timepoint

4 to 6 weeks after birth

Method of measurement

Check list

5

Description

The condition of chronic lung disease

Timepoint

4 to 6 weeks after birth

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Babies in need of surfactant receive exogenous surfactant + budesonide solution 0.25 mg / kg or 0.5 cc / kg which is injected into the face via an intratracheal catheter. Each infant is given only one dose of budesonide.

Category

Treatment - Drugs

2

Description

Control group: Infants who need surfactants receive exogenous surfactants which are injected into the face via an intratracheal catheter.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Amir-Mohammad Armanian

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Sofe Blvd, Isfahan Province, Isfahan

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Recruitment center

Name of recruitment center

Shahid Beheshti

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amir-Mohammad Armanian

Position

Associate Professor of Neonatal-Perinatal Medicine

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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