Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Budesonide Inhaler on chronic lung disease prevention in neonates with RDS and gestational age of lower than 28 weeks

Protocol summary

Summary

Considering all the recent outcomes of neonatal respiratory care, Bronchopulmonary Dysplasia, or BPD, is still the most prevalent reason of serious morbidity in premature neonates. The neonate's engagement in this process results in longer hospitalization, and in long term, difficulties in life. BPD is essentially a diagnosis based on pathologic findings, in which mechanical ventilation and oxygen contact in preterm lungs affiliated with RDS are among its most important pathogens. This disease is also known as Chronic Lung Disease or CLD. At present, CLD is defined with the need for supplementary oxygen for at least 28 days after birth. As the pathogens for CLD are multifactorial, approaches to this disease are focused on medical interventions and prevention. Due to the fact that the etymology of BPD involves mechanical ventilation, oxygen toxicity, infection processes, and inflammation as the core factors, a wide range of medicinal and non-medicinal approaches are introduced for its prevention and treatment. In the current study, an aerosol corticosteroid, namely Budesonide, is used to prevent BPD. The inclusion criteria involves neonates with less than 28 weeks of gestation, who are diagnosed with RDS and are treated with nCPAP and receive surfactant in the first two hours of birth. For the case group, administering aerosolized Budesonide starts at 12 hours after birth and continues each 12 hours for at least 7 days or as long as the neonate is under nCPAP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112810430N6**
Registration date: **2016-01-03, 1394/10/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Budesonide Inhaler on chronic lung disease prevention in neonates with RDS and gestational age of lower than 28 weeks

Public title

The Effect of Budesonide Inhaler on chronic lung disease prevention in neonates with RDS and gestational age of lower than 28 weeks

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: * 23 to 28 weeks gestational age. * compatible clinical symptoms of RDS (Respiratory Disease Syndrome) as (tachypnea, intercostal retraction, nasal flaring, grunting, and the need for supplemental oxygen). * letter of consent. Exclusion criteria: * congenital malformation. * prinatal asphyxia.
Age
To **7 days** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Isfahan University of Medical Sciences' Ethics Committee
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Approval date
2015-03-16, 1393/12/25
Ethics committee reference number
393918

Health conditions studied

1

Description of health condition studied
Chronic Lung Disease
ICD-10 code
J40
ICD-10 code description
Bronchitis, not specified as acute or chronic

Primary outcomes

1

Description
Chronic lung disease prevention
Timepoint
4 weeks after birth
Method of measurement
The need for supplementary oxygen

Secondary outcomes

1

Description
Reduction in need for surfactant
Timepoint
72 hours after birth
Method of measurement
The need for supplementary oxygen more than 40%

Intervention groups

1

Description
Intervention Group: Aerosolized Budezonide is administered at 12 hours from birth and is continued each 12 hours for at most one week
Category
Treatment - Drugs

2

Description
Control Group: In this group, Aerosolized Budesonide is not administered and the patients are just treated with nCPAP
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti and Alzahra Hospitals
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Dr. Alireza Sedeghnia
Street address
Alzahra Hospital
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty