

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the efficacy of Intravenous Dexamethasone and Budesonide Nebulizer in Infants Respiratory Distress Syndrome

Protocol summary

Summary

The aim of this randomized clinical trial is to compare the efficacy of Intravenous Dexamethasone and Budesonide Nebulizer in treatment of infants' Respiratory Distress Syndrome. The Target population is 60 infants. Preterm infants with respiratory distress syndrome admitted in NICU ward of our hospital will be assessed for eligibility. Infants with birth weight between 1000-2500 gr, Gestational age of less than 36 weeks, Mechanical ventilation for at least two days and Oxygen saturation of more than 30% after extubation will be included in the study. Patients with Hemorrhagic lesions, Congenital Anomalies, Chromosomal Anomalies, early sepsis and death before 72 hours of age will be excluded from the study. Patients will be randomly allocated to two groups; first group will receive 0.15 mg/kg of IV Dexamethasone (every 12 hours) and second group will receive 200 micrograms of Budesonide nebulizer every day for 3 to 5 days. Main outcome measures including respiratory rates, arterial oxygen saturation, distress and retraction and need for repeated intubation will be evaluated for assessing efficacy of treatment. Oxygen dependency, blood pressure, blood sugar, pneumonia, sepsis, pneumothorax and other adverse effects and complications will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101917413N20**

Registration date: **2016-11-02, 1395/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-02, 1395/08/12

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Pharmaceutical branch of Islamic Azad University

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Intravenous Dexamethasone and Budesonide Nebulizer in Infants Respiratory Distress Syndrome

Public title

Comparison of Intravenous Dexamethasone and Budesonide Nebulizer in treatment of Respiratory Distress Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: birth weight between 1000-2500 gr; Gestational age of less than 36 weeks; Mechanical ventilation for at least two days; Oxygen saturation of more than 30% after extubation; PH<7.2; PCO2>55; PaO2<50 Exclusion Criteria: Hemorrhagic lesions; Congenital Anomalies; Chromosomal Anomalies; early sepsis; death before 72 hours of age

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Committee on research ethics, pharmaceutical sciences branch, Islamic Azad University

Street address

Yakhchal st., Gholhak, Shariati st., Tehran, Iran

City

Tehran

Postal code

193956466

Approval date

2013-09-16, 1392/06/25

Ethics committee reference number

IR.IAU.PS.REC.1392.20

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Respiratory rate

Timepoint

before and after extubation

Method of measurement

one minute counting by nurse

2

Description

PH

Timepoint

before and after extubation

Method of measurement

Arterial Blood Gas Assessment

3

Description

Blood Pressure

Timepoint

before and after extubation

Method of measurement

Monitoring System

4

Description

Oxygen Saturation

Timepoint

before and after extubation

Method of measurement

Pulse Oxymetry

Secondary outcomes

empty

Intervention groups

1

Description

First group will undergo treatment with Intravenous Dexamethasone 0.15 mg/kg every 12 hours for 3 to 5 days

Category

Treatment - Drugs

2

Description

The second group will undergo treatment with inhaled budesonide through jet nebulizer (200 micrograms daily) for 3 to 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Najmiyeh Hospital

Full name of responsible person

Bitanajafian

Street address

Hafez, Jomhouri st., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Pharmaceutical Sciences
Branch, Islamic Azad University

Full name of responsible person

Farshaad Hashemian

Street address

Yakhchal st, Gholhak, Shariati st., Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Pharmaceutical Sciences
Branch, Islamic Azad University

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

Student Research Committee, Baqiyatallah University
of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Hossein Khosravi

Position

Secretary-General

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Pediatrics, Head and Neck Surgery,
Faculty of Medicine, Baqiyatallah University of Med

Full name of responsible person

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Neonatalogist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Hossein Khosravi

Position

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Other areas of specialty/work

Street address

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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