

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparing the efficacy of Albuterol Nebulizer and Albuterol plus Budesonide Nebulizer in treatment of Respiratory Distress Syndrome

#### Protocol summary

##### Summary

The aim of this randomized clinical trial is to compare the efficacy of Albuterol Nebulizer and Albuterol plus 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 0.5 mg/kg of Albuterol Nebulizer (every 8 hours) and second group will receive Albuterol plus Budesonide Nebulizer (400 mcg/kg) every 12 hours 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: **IRCT2016111617413N22**  
Registration date: **2016-11-26, 1395/09/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-26, 1395/09/06

#### Registrant information

##### Name

Hamidreza Karimi-Sari

##### Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 4354

##### Email address

hrkarimisari@bmsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

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

#### Expected recruitment start date

2015-09-23, 1394/07/01

#### 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

Comparing the efficacy of Albuterol Nebulizer and Albuterol plus Budesonide Nebulizer in treatment of Respiratory Distress Syndrome

#### Public title

Comparing the efficacy of Albuterol Nebulizer and Albuterol plus 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; PCO<sub>2</sub>>55; PaO<sub>2</sub><50. Exclusion criteria: hemorrhagic lesions; congenital anomalies; chromosomal anomalies; early sepsis; death before 72 hours of age.

**Age**

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****Approval date**

2015-09-16, 1394/06/25

**Ethics committee reference number**

IR.IAU.PS.REC.1394.28

**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**

pH

**Timepoint**

before and after intervention

**Method of measurement**

Arterial Blood Gas Assessment

**2****Description**

Respiratory rate

**Timepoint**

before and after intervention

**Method of measurement**

one minute counting by nurse

**3****Description**

Blood Pressure

**Timepoint**

before and after intervention

**Method of measurement**

Monitoring System

**4****Description**

Oxygen Saturation

**Timepoint**

before and after intervention

**Method of measurement**

Pulse Oxymetry

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The second group will undergo treatment with inhaler Albuterol plus Budesonide through jet nebulizer (400 mcg every 12 hours) for 3 to 5 days.

**Category**

Treatment - Drugs

**2****Description**

First group will undergo treatment with Albuterol Nebulizer 0.5 mg/kg every 8 hours 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****Street address**

Nosrati Alley, Sheykh Bahaei st, Mollasadra st., Vanaq  
sq., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8862 0826

**Fax****Email**

dr.mhkhosravi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Department of Pediatrics, Faculty of Medicine,  
Baqiyatallah University of Medical Sciences, Tehran,

**Full name of responsible person**

Bitanajafian

**Position**

Neonatalogist

**Other areas of specialty/work****Street address**

Nosrati Alley, Sheykh Bahaei st, Mollasadra st., Vanaq  
sq., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8862 0826

**Fax****Email**

bitanajafian@bmsu.ac.ir

**Web page address**

## Person responsible for updating data

#### 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****Street address**

Nosrati Alley, Sheykh Bahaei st., Mollasadra st.,  
Vanaq sq., Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8862 0826

**Fax****Email****Web page address**

## 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*