

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of inhaled Salbutamol (Ventolin) before intratracheal surfactant on the outcomes of Respiratory distress syndrome of newborn

#### Protocol summary

##### Study aim

determination of effect of salbutamol on respiratory distress syndrome

##### Design

Clinical trial with control group, with parallel groups, single blinded, randomized by random computer numbers, phase 3 clinical trial - study on 62 patients.

##### Settings and conduct

A study is being conducted on the disease of respiratory distress syndrome in premature infants. The place of study is in the neonatal intensive care unit in Yas and Bahrami hospitals. Newborns admitted to these wards enter the study after obtaining informed consent if they meet the entry requirements. 30 minutes before surfactant administration, arterial blood gas test and oxygen saturation are performed and in the intervention group, inhalational salbutamol is nebulized. 30 minutes later, arterial blood gas test is performed again and oxygen saturation is measured. And the results is compared.

##### Participants/Inclusion and exclusion criteria

Include: Respiratory distress syndrome diagnosis and candidation for surfactant. Exclude: other respiratory problems (Transient tachypnea of newborn, meconium aspiration, pneumonitis, congenital diaphragmatic hernia , Apgar score under 3 min5, heart rate more than 180, chromosomal disorder, Cardiac malformations, asphyxia, obstetric trauma, Twin to twine transfusion , sepsis, severe metabolic acidosis, Congenital tumors, maternal diabetes, asthma, Death in first day

##### Intervention groups

In the intervention group: salbutamol with standard dose (0.2 mg / kg/d) willbe nebulized as a single dose, 30 minutes before surfactant administration. In the control group, routine treatment willbe performed.

##### Main outcome variables

Oxygen saturation and arterial CO2 partial pressure  
Duration of hospitalization, duration of need for intubation or continuous positive airway pressure ,

neonatal outcome (mortality rate)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200805048312N1**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

##### Registration date

2020-10-28, 1399/08/07

##### Registrant information

##### Name

Seyyed Mohsen Sadatinejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7301 3000

##### Email address

sadatinezhad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2022-09-23, 1401/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of inhaled Salbutamol (Ventolin) before intratracheal surfactant on the outcomes of Respiratory distress syndrome of newborn

### Public title

The effect of inhaled Salbutamol on improvement of newborns with Respiratory distress syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Informed parent's consent Diagnosis of respiratory distress syndrome due to clinical and Para clinical data and candidation of intertracheal surfactant injection

#### Exclusion criteria:

Other respiratory disease such as Transient tachypnea of newborn, meconium aspiration, pneumonia, congenital diaphragmatic hernia Arrhythmia, heart rate more than 180 5th minute respiratory appgar under 3 Congenital heart malformation, chromosomal malformation Asphyxia, severe hypoxia Birth trauma Hydrops Twin to twin transfusion Sepsis Severe Metabolic acidosis Electrolyte disorder, hypoglycemia, polycythemia History of maternal diabetes or asthma Death in first day of life Congenital tumors

### Age

From **1 day** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **62**

### Randomization (investigator's opinion)

Randomized

### Randomization description

After admission of newborns and diagnosis of respiratory distress syndrome, patient that candidate for administration of intertracheal surfactant will be enter to the study. Patients randomly will be allocate to control and intervention group. Random allocation will be done by use of random number produced by digital calculator. If the number would be multiple of 2, patient will be allocate in intervention group and if not, patient will be allocate in control group.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Before acceptance informed consent for participating in this study, parent will be inform that why and how, salbutamol will be administrate for newborns. But Parent will not be inform whether their baby receive Salbutamol or not.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of medical children's center

##### Street address

62 Qarib St. , Keshavarz Blvd., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733151

#### Approval date

2020-09-24, 1399/07/03

#### Ethics committee reference number

IR.TUMS.CHMC.REC.1399.128

## Health conditions studied

### 1

#### Description of health condition studied

Respiratory distress syndrome

#### ICD-10 code

P22.0

#### ICD-10 code description

Respiratory distress syndrome of newborn

## Primary outcomes

### 1

#### Description

oxygen saturation (%)

#### Timepoint

at time of nebulizing of salbutamol and 30 minute after injection of intratracheal surfactant

#### Method of measurement

Pulse oxymetry

### 2

#### Description

arterial partial pressure of CO<sub>2</sub> (PaCO<sub>2</sub> )

#### Timepoint

at time of nebulizing of salbutamol and 30 minute after injection of intratracheal surfactant

#### Method of measurement

ABG test (Artrial blood gas)

## Secondary outcomes

### 1

#### Description

length of hospitalization (days)

#### Timepoint

at the time of discharging

#### Method of measurement

Patient file

### 2

#### Description

need for mechanical ventilation (duration)

#### Timepoint

at the time of extubation

#### Method of measurement

Patient file

### 3

#### Description

need for continuous positive airway pressure (CPAP)

#### Timepoint

at the time of discontinuing of CPAP

#### Method of measurement

Patient file

### 4

#### Description

outcome (death or live)

#### Timepoint

at the time of discharging

#### Method of measurement

Patient file

## Intervention groups

### 1

#### Description

Intervention group: nebulizing single dose of inhalational salbutamol (asthalin®) from Cipla (india) , 30 minute before injection of intratracheal surfactant. dosage : 0.2 mg per kg

#### Category

Treatment - Drugs

### 2

#### Description

Control group: routine health care and treatment

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Bahrami Pediatrics hospital- NICU

#### Full name of responsible person

Kamyar Kamrani

#### Street address

Shahid Kiyayi alley(Ghasemabad) , Damavand street, tehran

#### City

tehran

#### Province

Tehran

#### Postal code

1641744991

#### Phone

+98 21 7301 3000

#### Email

hosp\_bahrami@tums.ac.ir

#### Web page address

<https://enbahrami.tums.ac.ir/>

### 2

#### Recruitment center

#### Name of recruitment center

Yas hospital- NICU

#### Full name of responsible person

MohammadReza Zarkesh

#### Street address

Sarve st, Nejatollahi shomali st, Karimkhan st

#### City

tehran

#### Province

Tehran

#### Postal code

1598718311

#### Phone

+98 21 8894 8217

#### Fax

#### Email

yashospital@gmail.com

#### Web page address

<http://medicine.tums.ac.ir/yas>

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

MohammadAli Sahrayiyan

#### Street address

Vice Chancellor for Research and Technology, sixth floor, Central Organization of the University, Ghods Street, Keshavarz Boulevard

#### City

tehran

#### Province

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#### Postal code

1111111111

**Phone**

+98 21 8163 3686

**Email**

vcr@tums.ac.ir

**Web page address**

https://vcr.tums.ac.ir/

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Kamyar Kamrani

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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

Tehran University of Medical Sciences

**Full name of responsible person**

Kamyar Kamrani

**Position**

Associate professor

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Tehran University of Medical Sciences

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**Postal code**

1641744991

**Phone**

+98 21 7301 3000

**Email**

kamyarkamrani48@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

After completing and analysing the study we will submit the title and details in an ISI approved magazine of neonate

**When the data will become available and for how long**

After deadline of completion and for ever

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Under criteria of respiratory distress syndrome, data could be used

**From where data/document is obtainable**

From magazine website that publish the study, google scholar and maybe pubmed or scopus Email :sadtinejad71@gmail.com Tel:09378070876

**What processes are involved for a request to access data/document**

According to financial policy of publisher

**Comments**