# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 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 saturaton are performed and in the intervention group, inhalational salbutamol is nebulized. 30 minutes later, arterial blood gas test is performed again and oxygen saturaton 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 saturaton 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 interatrachial surfactant injection

**Exclusion criteria:**
Other respiratory disease such as Transient tachypnea of newborn, meconium aspiration,pneumonitis, congenital diaphragmatic hernia Arrhythmia, heart rate more than 180 5th minute respiratory apgar under 3 Congenital heart malformation, chromosomal malformation Asphyxia, severe hypoxia Birth trauma Hydrops Twin to twin transfusion Sepsis Severe Metabolic acidosis Electrolyte disorder, hypoglycemia, polycytemia 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 willbe enter to the study. Patients randomly willbe allocate to control and intervention group. Random allocation willbe done by use of random number produced by digital calculator. If the number would be multiple of 2, patient willbe allocate in intervention group and if not, patient willbe allocate in control group.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Before acceptance informed consent for participating in this study, parent willbe inform that wwhy and how, salbutamol willbe administrate for newborns. But Parent willnot 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 CO2 (PaCO2 )

**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 af 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: nebulizzing 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
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**Province**
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**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**
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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

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Kamyar Kamrani
**Position**
Associate professor
**Latest degree**
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Tehran
**Postal code**
1641744991
**Phone**
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**Email**
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## 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 scholor and maybe pubmed or scopus Email :sadatinejad71@gmail.com Tel:09378070876

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

According to financial policy of publisher

**Comments**