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 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
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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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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
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Tehran
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

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Person responsible for updating data

Contact

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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 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