Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

To Investigate the Efficacy of Inhaled Epinephrine in Extubation of Preterm Neonates in Neonatal Intensive Care

Protocol summary

Study aim
To Investigate the Efficacy of Inhaled Epinephrine in Extubation of Preterm Neonates in Neonatal Intensive Care

Design
This study is a double-blind parallel clinical trial in which60 infants are divided into control and intervention groups. To evaluate the effect of inhaled epinephrine on the success rate of extubation of intubated neonates over 3 days

Settings and conduct
This study was performed on 60 neonates with intubation for more than 3 days. Immediately after extubation, half a cc of epinephrine 1/10000 or distilled water is used every three hours, which is reduced to 72 times. Using a ver.1.1 Random number generator, a list of random numbers will be generated. It is a double-blind study.

Participants/Inclusion and exclusion criteria
The causes of premature infants and intubation are more than 3 days in the neonatal intensive care unit of Shariati Hospital in Tehran. Exclusion criteria are infants with chronic lung disease and chronic heart or nerve disease, and infants with genetic and syndromic diseases, as well as term infants over 34 weeks and weighing less than 1700 grams.

Intervention groups
To evaluate the effect of inhaled epinephrine on the success rate of neonatal extubation, 112 intubated neonates over 3 days were randomly divided into two groups receiving inhaled epinephrine immediately after extubation or distilled water intake group. 0/5 cc L-Epinephrine 1/10000 were nebulized every three hours to 24 hours. Then reduce the frequency to 72 hours from the time it starts until it stops in 72 hours.

Main outcome variables
Vital signs (heart rate, blood pressure, and respiration rate), respiratory distress, and stridor after intubation, the number of re-intubations, the duration of intubation, and the length of time the infant was admitted to the ward are recorded in the records.

General information

Reason for update
Due to the insufficient number of patients in the last 2 years, 60 patients were included in the study, 6 of whom died, and data analysis was performed on 54 infants.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210607051507N4**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **prospective**

Last update: **2023-12-27, 1402/10/06**
Update count: **2**

Registration date
2021-11-17, 1400/08/26

Registrant information

Name
Ameneh Lamsehchi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
2021-11-22, 1400/09/01

Actual recruitment end date
2023-09-21, 1402/06/30
Trial completion date
2023-10-22, 1402/07/30

Scientific title
To Investigate the Efficacy of Inhaled Epinephrine in Extubation of Preterm Neonates in Neonatal Intensive Care

Public title
To Investigate the Efficacy of Inhaled Epinephrine in Extubation of Preterm Neonates in Neonatal Intensive Care
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Premature infants with intubation for more than 3 days in the neonatal intensive care unit of Shariati Hospital in Tehran
Exclusion criteria:
Chronic lung disease Chronic heart disease nerve disease infants with a genetic and syndromic disease term infants over 34 weeks and weighing less than 1700 grams.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **112**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients were randomized into the two study groups of intervention with inhaled epinephrine or distilled water (placebo) with the method of shuffling a deck of cards named A or B placed in covered envelopes and block randomization designed in 15 blocks of 4 matched subjects (ABAB, AABB, ABBA BBAA, BAAB, BABA), got ready by one of the study persons who was not participating in the process of allocating of the agents or was not connected to patients or even the therapist. The final sample was randomly allocated into the two study arms with an equal size of 30 neonates.
Blinding (investigator's opinion)
Double blinded
Blinding description
Because it is a double-blind clinical trial, a randomized list is provided to the pharmacist to produce a sequence that fits the drug packages so that it is identical in appearance and so on. The packages will then be given to the therapist. Appointment treatment will be given to patients according to the order of tablets from 1 to 60, which includes 30 syringes containing epinephrine for incense and 30 syringes containing distilled water for incense, which was done by the pharmacist according to a random list. After the pharmacist prepares the drugs, he will deliver them to the researcher and the researcher will provide them to the therapist. In this case, the therapist does not know which patient is receiving which treatment after randomization.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Room 605, sixth floor, corner of Ghods st.,Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
42911450
Approval date
2021-09-23, 1400/07/01
Ethics committee reference number
IR.TUMS.CHMC.REC.1400.122

Health conditions studied

1

Description of health condition studied
To Investigate the Efficacy of Inhaled Epinephrine in Extubation of Preterm Neonates in Neonatal Intensive Care
ICD-10 code
T88.4
ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
Pco2 in ABG

Timepoint
Six hours after extubation in the target group and placebo
Method of measurement
ABG

2

Description
FIO2 percent
Timepoint
24 hours after the start of epinephrine or stilled water after extubation
Method of measurement
Record of ventilator

3

Description
High blood pressure
Timepoint
24 hours after extubation
Method of measurement
Pressure control machine

4

Description
Tachycardia (a heart rate above 180 beats per minute in the baby)
Timepoint
24 hours after extubation
Method of measurement
cardiac monitoring

5

Description
Tachypnea (the number of breaths above 60 per minute in the baby)
Timepoint
24 hours after extubation
Method of measurement
Counted by the nurse and recorded in the file

6

Description
Surfactant requirement
Timepoint
During hospitalization
Method of measurement
Extraction from the patient file

7

Description
Death
Timepoint
During hospitalization
Method of measurement
Extraction of patient file

8

Description
Reintubation after extubation failure
Timepoint
During hospitalization
Method of measurement
Extract from the file

9

Description
Intubation time
Timepoint
Hospitalization duration
Method of measurement
Extract from file

10

Description
Duration of mechanical ventilation
Timepoint
Duration of mechanical ventilation
Method of measurement
Extract from file

11

Description
The age of the baby at the time of intubation
Timepoint
The age of the baby at the time of intubation
Method of measurement
Extract of file

12

Description
Gender of the baby
Timepoint
In hospitalization
Method of measurement
Extract from file

13

Description
Gestational age
Timepoint
Hospitalization
Method of measurement
Extract from file

Secondary outcomes

1

Description
Duration of non-invasive mechanical ventilation such as NIPPV.NCPAP after extubation
Timepoint
After extubation

Method of measurement
Extract from file

Intervention groups

1

Description
Intervention group: 0.5 cc per kg L-epinephrine 1/10000 were used as every three hours to 24 hours. Then reduce the frequency to 72 hours from the time of onset to interruption in 72 hours
Category
Treatment - Devices

2

Description
Control group: Half a cc per kilogram of infant weight was distilled every three hours to 24 hours. Then reduce the frequency to 72 hours from the time of onset to interruption in 72 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Setareh Sagheb
Street address
Jalal Al-Ahmad Three Ways, North Kargar Street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Ameneh Lamsehchi
Position
Non-faculty specialist
Latest degree
Specialist
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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
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
No - There is not a plan to make this available