

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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 which 60 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)

Phone

+98 21 6656 1315

Email address

lamsehchila@gmail.com

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 stiller 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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ameneh lamsehchi

Street address

Central Organization of Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd.,

City

Tehran

Province

Tehran

Postal code

81633125

Phone

+98 21 8163 3102

Email

itcenter@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

Ameneh Lamsehchi

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Central Organization of Tehran University of Medical Sciences, corner of Ghods Street, Keshavarz Boulevard,

City

Tehran

Province

Tehran

Postal code

81633125

Phone

+98 21 8163 3102

Email

lamsehchila@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Setareh Sagheb

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shariati Hospital, Jalal Al-Ahmad Three Ways, North

Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

00084901-021

Email

dr.ssagheb@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ameneh Lamsehchi

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Central Organization of Tehran University of Medical

Sciences, corner of Ghods Street, Keshavarz

Boulevard,

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3102

Email

Lamsehchila@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

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