Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effects of remifentanyl combined with atropine with fentanyl and remifentanyl alone on vital signs in non-emergent intra-tracheal intubation in preterm neonates

Protocol summary

Study aim

The goal of this study is comparison the effects of fentanyl, remifentanyl and atropine combined with remifentanyl on vital signs in non-emergent intra-tracheal intubation in preterm neonates.

Design

In this study 75 cases will be divided into 3 groups: 1) Fentanyl 2 µg/kg and then intubation 2) Remifentanyl 1µg/kg and then intubation 3) Atropin 20 µg/kg plus Remifentanyl 1µg/kg and then intubation. Simple randomization using RandList software (v:1.2) and double blind study will be used Physician in attendance and nurse will be blind in this study

Settings and conduct

The study will be conducted in the Pediatrics and Alzahra hospital neonatal intensive care units.Based on the inclusion criteria, infants will be divided into three groups, and in each group, the effectiveness of existing analgesics will be examined, so that the therapist and information analyzer will not be aware of the used drugs and will recognize them based on the code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Preterm neonates (27-34 week-old) in need of intubation and surfactant administration 2) Without any major anomalies 3) Parents agree to participate in research 4) Respiratory Score of neonates under 8 based on acute critical care of neonates
Exclusion criteria: 1) No need for intubation 2) Major anomalies 3) Neonates with family history of Myasthenia gravis

Intervention groups

27-34 weeks neonates in need of temporary intubation in three groups receive the following treatments: 1) Fentanyl 2 µg/kg and then intubation 2) Remifentanyl 1µg/kg and then intubation 3) Atropin 20 µg/kg plus Remifentanyl 1µg/kg and then intubation

Main outcome variables

Systemic blood pressure Heart rate hypoxia severity

General information

Reason for update

Acronym

INSUR - ACORN

IRCT registration information

IRCT registration number: **IRCT20160102025811N3**
Registration date: **2020-02-04, 1398/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-04, 1398/11/15**
Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Mirhadi Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

drmussavihadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of remifentanyl combined with atropine with fentanyl and remifentanyl alone on vital signs in non-emergent intra-tracheal intubation in preterm neonates

Public title

Comparison the effects of analgesic drugs on vital signs in intra-tracheal intubation in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm neonates (27-34 week-old) in need of Surfactant administration Without any major anomalies Parents agree to participate in research Respiratory Score of neonates under 8 based on Critical care of the neonate

Exclusion criteria:

No need for intubation Neonates with family history of Myasthenia gravis Major anomalies

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random numbers 75 samples will be divided into 3 groups using RandList software (v:1.2) physician in attendance and nurse will be blind in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs used in this study will be prepared in same shape and color syringes by someone who will not be aware of the process of study. Syringes will be given under the title A, B and C, to clinical caregiver and researcher. Clinical data analyzer will not have any information about the type of drug in the syringes. The content on each syringes will be declared for data monitoring team after completing the data analysis .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2019-10-28, 1398/08/06

Ethics committee reference number

IR.TBZMED.REC.1398.793

Health conditions studied

1

Description of health condition studied

Neonates with respiratory distress

ICD-10 code

P22

ICD-10 code description

Respiratory distress of newborn

Primary outcomes

1

Description

Systemic blood pressure

Timepoint

1-3 days old

Method of measurement

Monitoring device

2

Description

Heart rate

Timepoint

1-3 days old

Method of measurement

Monitoring device

3

Description

hypoxia severity

Timepoint
1-3 days old
Method of measurement
Pulsoxymeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1) Fentanyl 2 µg/kg and then intubation
Category
Treatment - Drugs

2

Description
Intervention group:2) Remifentanyl 1µg/kg and then intubation
Category
Treatment - Drugs

3

Description
Intervention group: 3) Atropin 20 µg/kg plus Remifentanyl 2µg/kg intravenous and then intubation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital and Tabriz AL-Zahra Hospital
Full name of responsible person
MirHadi Mousavi
Street address
Sheshgelan st.Children's Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2255
Email
mirhadimousavi33@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Sameay
Street address
Golgasht St.Deputy Research and Technology
City
Tabriz
Province
East Azarbaijan
Postal code
5165995131
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Web page address
https://researchvice.tbzmed.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
MirHadi mousavi
Position
Assistant Prof.
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Sheshgelan St.Childreen Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2255

Email
mirhadimousavi33@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
MirHadi Mousavi
Position
Assistant Prof.
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Seshgelan St, Children Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 41 3526 2255
Email
mirhadimousavi33@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mihadi mousavi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Sheshglan St, Children Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5136735886
Phone
+98 35262279
Email
mirhadimousavi33@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The whole data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period 3 months after printing results
To whom data/document is available
Data will only be available to researchers working in academic and academic institutions
Under which criteria data/document could be used
Using the findings will not be a problem with the source
From where data/document is obtainable
By sending a request to the email: mirhadimousavi33@yahoo.com
What processes are involved for a request to access data/document
- Sending a request to the email with the applicant's scientific and academic documentation - Submit the requested documentation within a week to the applicant
Comments