

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

drmussaviahadi@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.Children 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