

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Remifentanil versus Fentanyl for pain control during elective endotracheal intubation for surfactant administration in preterm neonates

Protocol summary

Summary

The aim of this study is comparison the effectiveness of remifentanil versus fentanyl in pain control during elective endotracheal intubation for surfactant administration in preterm infants. Preterm newborns with gestational age between 28 weeks to 34 weeks and 6 days from last menstrual period and have respiratory distress according to clinical evaluation, after receiving consent of parents will be divided in two groups by random sampling. Neonates in group 1, receive 2 microgram per kilogram intravenous fentanyl infusion and neonates in group 2, receive 1 microgram per kilogram of the drug. In both groups drug infusion will be start 1 minute before intubation, and drug infusion time in both groups will be 2 minutes. In each group, we will take a film before, during and after procedures of the intubation with a camera. The vital signs consist of heart rate, oxygen saturation and change in facial grimace will be documented in not named PIPP-R (Premature Infant Pain Profile-Revised) scoring sheet for each infant prior, during and after drug administration. All films and data will be interpreted and scored by one NIDCAP (Newborn Individualized Developmental Care and Assessment Program)-trained attending professor, who is blind about the type of the drug used in infant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310164113N7**
Registration date: **2017-05-07, 1396/02/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-07, 1396/02/17

Registrant information

Name

Mohammad Bagher Hosseini

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Remifentanil versus Fentanyl for pain control during elective endotracheal intubation for surfactant administration in preterm neonates

Public title

Remifentanil versus Fentanyl for pain control during elective endotracheal intubation in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preterm newborns with gestational age between 28 to 34 weeks and 6 days from last menstrual period of mother who was born in Alzahra teaching hospital of Tabriz; clinical criteria of respiratory distress (consists of: tachypnea, grunting, inter costal retraction and increased oxygen requirement) and radio graphic findings of Respiratory Distress Syndrome; need for surfactant treatment by INSURE (Intubate, Surfactant, Extubate) procedure. Exclusion criteria: other causes of respiratory distress in newborns; second or third degree AV heart block; use of fentanyl during 4 hours from delivery; severe asphyxia (APGAR score under 5 at 5th minutes after delivery); impaired consciousness level; major congenital anomalies; difficult intubation due to facial anomalies; more than three attempts for intubation.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in Research Committee of Tabriz medical university

Street address

Tabriz University of Medical Sciences , Golgasht avenue

City

Tabriz

Postal code

Approval date

2016-12-06, 1395/09/16

Ethics committee reference number

IR.TBZMED.REC.1395.993

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Hyaline membrane disease

Primary outcomes

1

Description

Pain Score

Timepoint

During endotracheal intubation

Method of measurement

PIPP-R pain assessment tool (Premature Infant Pain Profile-Revised)

Secondary outcomes

1

Description

Time need for succesfull intubation

Timepoint

From starting time of intubation prosedures

Method of measurement

Seconds

2

Description

Chang in heart rate, pulesxymetry amd blood pressure

Timepoint

Before, during and after endotracheal intubation

Method of measurement

Manitoring by automatic monitor and record of blood pressure by appropriate cuff

3

Description

Number attempts for a successful intubation

Timepoint

During endotracheal intubaion

Method of measurement

Observation

4

Description

Apnea (stoping of respiration more than 20 seconds)

Timepoint

During intubation prosedures

Method of measurement

Observation and recording

5

Description

Sever hypoxia (O2 saturaion<70%)

Timepoint

During and after endotracheal intubation

Method of measurement

Manitoring by automatic monitor

6

Description

Chest rigidity

Timepoint

During and after endotracheal Intubation

Method of measurement

Observation and recording

7

Description

Need for use of Naloxan

Timepoint

After endotracheal intubation

Method of measurement

Observation and recording

8

Description

Intraventricular hemorrhage grade 2 and more

Timepoint

Day 3

Method of measurement

Ultrasonography with portable Sonoraphy device

Intervention groups

1

Description

Neonates in group1, one minute before intubation
recieve 2 microgram per kilogram slow intravenous
Fentanyl (manufactured by Abureyhan company)infusion
in 2 minutes.

Category

Treatment - Drugs

2

Description

Neonates in group 2, one minute before intubation
recieve 1 microgram per kilogram slow intravenous
Remifentanil (manufactured by Mylan company) infusion
in 2 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital of Tabriz

Full name of responsible person

Mohammadbagher Hosseini

Street address

Artesh Avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of of
Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

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Tabriz University of Medical Sciences , Golgasht
avenue,No 2 Central Building,third floor

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Tabriz University of of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammadbagher Hosseini MD

Position

Associate Professor of Neonatology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty