# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison of the Effect of Atropine Alone and in Combination with Midazolam on the Prevention of Pain of Endotracheal Intubation in Premature Neonates with Respiratory Distress

## Protocol summary

**Study aim**

Comparison of the effect of Atropine alone and in combination with Midazolam on mean of pain score of endotracheal intubation in premature neonates with respiratory distress.

**Design**

This study is a two arm parallel group double blinded phase 2 clinical trail. During the study period 105 newborn infants were included and eventually 80 newborns were evaluated which divided in to case and control group equally

**Settings and conduct**

This study was doneon premature patients who admitted to the NICU ward at Alzahra and ShahidBeheshti University hospitals, Isfahan, Iran.If patient meet the eligible critria divided to Two group according to the odd or even numbers of document and recieved the drug package A or B and record the degree of pain and changes of vital sign before and after intubation

**Participants/Inclusion and exclusion criteria**

Patients were newborns with gestational age of less than 37 weeks who had respiratory distress syndrome and needed nasal continuous positive airway pressure with a fraction of inspiration oxygen of at least 40% to maintain oxygen saturation between 90 to95% and were candidates for intubation,surfactant and rapid extubation. Enrolled patients with maxillofacial anomalies, congenital heart diseases or previous intubation were not included in the study. Patients who underwent 2 or more failed attempts for intubation were excluded from the study

**Intervention groups**

In intervention group neonates receive Midazolam with Atropine five minute before intubation and in control group neonates receive Atropine five minute before intubation

**Main outcome variables**

Pain Score; Heart Rate; Arterial Blood Pressure; Arterial Oxygen Saturation Percent; Number of Attempts for Intubation and Duration of Intubation.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20130329012869N2**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**
Update count: **0**

**Registration date**

2020-06-09, 1399/03/20

**Registrant information**

**Name**

zohreh badiee

**Name of organization / entity**

Isfahan university of medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 1668 5555

**Email address**

badiei@med.mui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-07-02, 1398/04/11

**Expected recruitment end date**

2020-07-01, 1399/04/11

**Actual recruitment start date**

2019-07-02, 1398/04/11

**Actual recruitment end date**

2020-07-01, 1399/04/11

**Trial completion date**

2020-07-01, 1399/04/11

**Scientific title**

Comparison of the Effect of Atropine Alone and in Combination with Midazolam on the Prevention of Pain of Endotracheal Intubation in Premature Neonates with Respiratory Distress

**Public title**

Premedication with Intravenous Midazolam for Neonatal Endotracheal Intubation

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Gestational age of less than 37 weeks Presence of respiratory distress syndrome and the need for nasal continuous positive airway pressure (Nasal CPAP)with a fraction of inspired oxygen (Fio2)of at least 40% to maintain arterial oxygen saturation between 90 to95% To be a candidate for surfactant treatment with Intubation Surfactant Rapid Extubation ( INSURE) method

**Exclusion criteria:**

Maxillofacial anomalies, congenital heart diseases Previous endotracheal intubation Twice or more failed attempts for intubation

**Age**

From **1 day** old to **30 days** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **105**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Midazolam with atropine and atropine alone are put in different packages called A and B by some one who dose not involve in this study

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

research ethics committee of Isfahan University of Medical

**Street address**

No 26- Laleh Ave- Boozarjomehr Blvd- 2nd Moshtagh - Esfahan city

**City**

Esfahan

**Province**

Isfehan

**Postal code**

8158857171

**Approval date**

2016-06-06, 1395/03/17

**Ethics committee reference number**

Ir.mui.rec.1395.3.018

## Health conditions studied

### 1

**Description of health condition studied**

pain during endotracheal intubation

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Pain Score

**Timepoint**

Before intervention and immediatly after intubation

**Method of measurement**

Premature Infant Pain Profile (PIPP)

## Secondary outcomes

### 1

**Description**

Heart Rate

**Timepoint**

At the beginning of the study; before drug injection; immediately after intubation and 10 minutes after intubation.

**Method of measurement**

Observation and pulse oxymeter

### 2

**Description**

Arterial Blood Pressure

**Timepoint**

At the beginning of the study; before drug injection; immediately after intubation and 10 minutes after intubation.

**Method of measurement**

Observation and pulse oxymeter

**3**

**Description**

Arterial Oxygen Saturation Percent

**Timepoint**

At the beginning of the study; before drug injection; immediately after intubation and 10 minutes after intubation.

**Method of measurement**

Observation and pulse oxymeter

**4**

**Description**

Number of Attempts for Intubation

**Timepoint**

During the intubation

**Method of measurement**

Observation

**5**

**Description**

Duration of Intubation

**Timepoint**

During the intubation

**Method of measurement**

Timer

## Intervention groups

**1**

**Description**

Intervention group:Injection of 150 microgram per kilogram midazolam intravenously in 5 minute and injection of 10 microgram per kilogram atropine intravenously 5 minute perior to intubation

**Category**

Prevention

**2**

**Description**

Control group: injection of 10 microgram per kilogram atropine intravenously 5 minute perior to intubation

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra University Hospital

**Full name of responsible person**

Zohreh Badiee

**Street address**

Hezar jarib Ave - Esfahan city

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**2**

**Recruitment center**

**Name of recruitment center**

Beheshti Univercity Hospital

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Vice chancellor of research of medicine univercity of esfahan

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**Email**

Research@mui.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Zohreh Badiee
**Position**
professor of pediatrics
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**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**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is 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
**Title and more details about the data/document**
Those information that related to main consequence is shareable
**When the data will become available and for how long**
after publication
**To whom data/document is available**
Employed researchers in univercity institutes
**Under which criteria data/document could be used**
Increasing knowledge of pediatricians and neonatologists Increasing the quality of health service Spreading the

consumption of premedication

**From where data/document is obtainable**

Send a massage to Badiei@med.mui.ac.ir WWW.journalonweb.com/jrms Send amassage to Dr.hamed zandi :Zandi 878@gmail.com

**What processes are involved for a request to access data/document**

Massaging with notice the Email address and title of research to the magazine office or one of the researchers then identify confirmation of applicant baseed on their documents and finally reply those data file considered that it will be take less than a week.

**Comments**