

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 trial. 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 done on premature patients who admitted to the NICU ward at Alzahra and Shahid Beheshti University hospitals, Isfahan, Iran. If patient meet the eligible criteria divided to Two group according to the odd or even numbers of document and received 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 to 95% 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 badiie

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1668 5555

Email address

badiiei@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 to 95% 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

Isfahan

Postal code

8158857171

Approval date

2016-06-06, 1395/03/17

Ethics committee reference number

lr.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 immediately 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 prior to intubation
Category
Prevention

2

Description
Control group: injection of 10 microgram per kilogram
atropine intravenously 5 minute prior to intubation
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra University Hospital
Full name of responsible person
Zohreh Badiie
Street address
Hezar jarib Ave - Esfahan city
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Esfahan
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Isfahan
Postal code
8158857171
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+98 31 3267 4572
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badiei@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Beheshti Univercity Hospital
Full name of responsible person
Zohreh Badiie
Street address
Hezar jarib Ave - Esfahan city
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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
Street address
Hezar jarib Ave - Esfahan
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Postal code
8174673441
Phone
+98 31 3793 2288
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 Badiie

Position

professor of pediatrics

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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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 university 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 message to Badiei@med.mui.ac.ir

WWW.journalonweb.com/jrms Send a message 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 based on their documents and finally reply those data file considered that it will be take less than a week.

Comments