Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of dexmedetomidine and atracurium in the ease of the tracheal after induction with propofol and sufentanil in children aged 6 to 12 years without neuromuscular relaxants

Protocol summary

Study aim

In this study, due to the limited studies that have been done in this field, we want to compare the rapid infusion of dexmedetomidine at the rate of 1 µg / kg with atracurium in improving the consequences of intubation without affecting hemodynamics in children after intubation with propofol and fentanyl. Let's pay

Design

a community-based, parallel-group, double-blind, randomized controlled trial, controlled clinical trial with a parallel-group design of 50 patients, randomized based on a random table of numbers.

Settings and conduct

The present study will be a prospective double-blind clinical trial in which fifty patients aged 6 to 12 years in the teaching hospitals of Mashhad University of Medical Sciences who are candidates for tracheal intubation under general anesthesia are available by sampling method.

Participants/Inclusion and exclusion criteria

Age between six to twelve years Candidates for tracheal intubation under general anesthesia who are candidates for elective surgery Asa physical condition score one and two Consent of the patient's guardian or legal guardian to enter the study

Intervention groups

Intervention group: Use of dexmedetomidine in combination with sufentanil and propofol Control group: Use of Atracurium in combination with sufentanil and propofol

Main outcome variables

Primary outcome: Success rate in intubation Secondary Outcome: Secondary Outcomes Including Hemodynamic Responses at Zero Time: Before Induction Time 1 After Induction and Before Intubation and Time Two One Minute After Intubation Measured in two groups and the incidence of complications in both groups and status scoring Intubation (scoring)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049177N1**
Registration date: **2021-05-24, 1400/03/03**
Registration timing: **retrospective**

Last update: **2021-05-24, 1400/03/03**
Update count: **0**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

Samira Ghanei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3611 2385

Email address

ghaneisamira@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-19, 1397/12/28

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of dexmedetomidine and atracurium in the ease of the tracheal after induction with propofol and sufentanil in children aged 6 to 12 years without neuromuscular relaxants

Public title
Comparison of the effect of dexmedetomidine and atracurium in the ease of the tracheal after induction with propofol and sufentanil in children aged 6 to 12 years without neuromuscular relaxants

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between six to twelve years Candidates for tracheal intubation under general anesthesia who are candidates for elective surgery Asa physical condition score one and two Consent of the patient's guardian or legal guardian to enter the study

Exclusion criteria:
Respiratory tract infection three weeks before intubation Children with cardiovascular disease Children have a difficult airway for intubation Children with morbid obesity (weight to height ratio more than 20%) Children with neuromuscular diseases Dissatisfaction of parents or legal guardians of patients to enter the study

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects will be randomly assigned into two groups of 25 patients with categories of 2 using the randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Sealed opaque envelopes will be used to conceal the sequencing. Accordingly, the participants were given codes and assigned into the 2 intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and intubation technicians were initially informed of the study process and its contents, but were unaware that participants were in the intervention or control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of medical Sciences

Street address
Razavi Khorasan Province, Mashhad, Ahmadabad Blvd, Department of Anesthesia and critical care, Dr. Mohammad Alipor

City
mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Approval date
2019-06-18, 1398/03/28

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.381

Health conditions studied

1

Description of health condition studied
Comparison of the effect of dexmedetomidine and atracurium in the ease of the tracheal after induction with propofol and sufentanil in children aged 6 to 12 years without neuromuscular relaxants

ICD-10 code
T88.4

ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
success rate in intubation

Timepoint
before intervention and 1 min after intervention

Method of measurement
Ease of intubation based on scoring table and intubation anesthesia partner checklist. Vital signs were recorded by monitoring. Includes sphygmomanometer .Pulse oximetry .Electrocardiogram

2

Description
Success rate in intubation in two groups/Hemodynamic responses
Timepoint
At zero time: before induction time one after induction and before intubation and time two one minute after intubation
Method of measurement
Scoring table / monitoring of blood pressure, heart rate and pulse oximetry

Secondary outcomes

1

Description
Secondary outcomes include hemodynamic responses at time zero: before induction, time one after induction and before intubation, and two minutes one minute after intubation measured in both groups and the incidence of complications in both groups and scoring the intubation status (scoring)
Timepoint
before intervention and 1 min after intervention
Method of measurement
the scoring method

Intervention groups

1

Description
Dexmedotidine group (A) and atracurium group (B). Patients in group A receive the following: Dexmedotidine 1 µg / kg + Propofol (3 mg / kg) + Su fentanyl (0.3 µg / kg)
Category
Treatment - Drugs

2

Description
Control group: Patients in group B will receive atracurium 0.5 mg / kg + propofol (3 mg / kg) + su fentanyl (0.3 µg / kg)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar hospital
Full name of responsible person
Mohammad Alipour
Street address
Mashhad- Medical University of Mashhad, Department of Anesthesia and Critical care
City
mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3841 7402
Email
ghaneisamira@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tafaghodi Mohsen
Street address
Mashahd- Daneshgah street- Ghoreyshi building- Reseach and technology Vice Chancellor
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Email
presidentoffice@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
DR. Mohammad Alipour
Position
Assistant Professor
Latest degree

Specialist

Other areas of specialty/work
Anesthesiology

Street address
Mashhad, Ghaem hospital, Department of Anesthesia and Critical care

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3841 7402

Email
alipourm@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Alipour Mohammad

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Mashhad, Ghaem hospital, Department of Anesthesia and Critical care

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3841 7402

Email
alipourm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Ghanei Samira

Position
assistant

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Mashhad, Ghaem hospital, Department of Anesthesia and Critical care

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3841 7402

Email
ghaneisamira@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
Part of the data, such as information about the main outcome

When the data will become available and for how long
Access period starts one year after the results are published

To whom data/document is available
Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
Only for researchers working in academic and scientific institutions

From where data/document is obtainable
Email

What processes are involved for a request to access data/document
2 months after receiving the application

Comments