

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 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)

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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

Dexmedetomidine group (A) and atracurium group (B). Patients in group A receive the following: Dexmedetomidine 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

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Mashhad- Medical University of Mashhad, Department of Anesthesia and Critical care

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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

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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

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Latest degree

Specialist

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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