

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Dexmedetomidine and Fentanyl on post intubation hemodynamic changes in children

Protocol summary

Study aim

Identification of the effects of Dexmedetomidine and Fentanyl on post intubation hemodynamic changes in children.

Design

randomized clinical trial with control groups, parallel groups , blinded ,randomized

Settings and conduct

this is a randomized clinical trial randomized by random numbers and two side blinded which will be done in imam hussein hospital isfahan 2019-2020.

Participants/Inclusion and exclusion criteria

enter:Children between 6 years to 12 years Candidate Surgery under General Anesthesia exit: difficult intubation ,duration of intubation more than 30 seconds ,more than one effort for intubation

Intervention groups

the participants are divided into 3 groups with 36 persons.and are divided by random allocation to 3 groups.drugs are coded and anesthesiologist does not know the groups. patients get to operation room after getting 0.1 mg/kg midazolam. first group gets 2 µ g/kg fentanyl 2 minutes before anesthesia,group 2 gets 2 µg/kg nasal dexmedetomidine 1 minutes before anesthesia , and group3 gets 2 µg/kg nasal normal saline .induction of anesthesia is by 2 µg/kg fentanyl and 5 mg/kg sodium thiopental and 0.5 mg/kg atracurium in all patients.

Main outcome variables

hemodynamic changes (systolic blood pressure,diastolic blood pressure, mean arterial pressure ,heart rate) before getting drugs, immediately after induction , immediately before layngoscopy and at 1,3,5,10 minutes after laryngoscopy and intubation in 3 groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191205045619N1**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

kiana golkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 9125

Email address

kianaamir2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-06-14, 1399/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Dexmedetomidine and Fentanyl on post intubation hemodynamic changes in children

Public title

Comparison of the effect of Dexmedetomidine and Fentanyl on post intubation hemodynamic changes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children between 6 years to 12 years Candidate Surgery under General Anesthesia

Exclusion criteria:

difficult intubation duration of intubation more than 30 seconds more than one effort for intubation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

random allocation

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicines are Delivered and Coded in Equal Volumes by the Researcher and the Anesthesiologist dose not know the groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University Medical Science

Street address

Building No.4, Isfahan University of Medical Sciences, Hezar Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.MUI.MED.REC.1398.358

Health conditions studied**1****Description of health condition studied**

Systolic blood pressure

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

diastolic blood pressure

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Pulse rate

ICD-10 code**ICD-10 code description****4****Description of health condition studied**

Respiratory rate

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

mean of SBP

Timepoint

before getting drugs, immediately after induction , immediately before layngoscopy and at 1,3,5,10 minutes after laryngoscopy and intubation.

Method of measurement

MONITORING BY MANOMETR

2**Description**

mean of DBP

Timepoint

before getting drugs, immediately after induction , immediately before layngoscopy and at 1,3,5,10 minutes after laryngoscopy and intubation.

Method of measurement

MONITORING BY MANOMETR

Secondary outcomes

empty

Intervention groups

1

Description

First group gets 2 mcg/kg fentanyl 1 minutes before induction .In all groups we will compare hemodynamic changes before and immediately after intubation.

Category

Treatment - Drugs

2

Description

Second group gets 2 mcg/kg nasal dexmedetomidine 1 minute before induction.all groups we will compare hemodynamic changes before and immediately after intubation.

Category

Treatment - Drugs

3

Description

Third group gets 2 mcg/kg as placebo 1 minute before induction.all groups we will compare hemodynamic changes before and immediately after intubation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Amir Shafa

Street address

Emam Khomeini Ave

City

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Postal code

815163381

Phone

+98 31 3386 6566

Email

emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Hezar Jerib Ave

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Isfahan

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Isfahan

Postal code

7346181746

Phone

+98 31 3792 9017

Email

sh_haghjoo@med.mui.ac.ir

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

Amir Shafa

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

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Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

information of participants and results of the study

When the data will become available and for how long

1 year after publish of the letter

To whom data/document is available

all of the researchers that are interested to have access to these information

Under which criteria data/document could be used

by sending request

From where data/document is obtainable

the projects admin

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

by email

Comments