Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of intranasal dexmedetomidine and remifentanil on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

Protocol summary

Study aim

Comparison the effect of intranasal dexmedetomidine and remifentanil on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

Design

This study is a double-blind, randomized, clinical trial study. The minimum required sample size was determined using the formula 35 in each group. Patients are classified into three groups using the random numbers table.

Settings and conduct

This clinical trial study will be done at Imam Hossein Hospital in Isfahan.The way of blinding is that the drugs are prepared and encoded in similar syringes and similar volumes.And the researcher and the anesthetist and the patient do not know about the location of the patients in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes all children ages 6 to 12 years of age who have a general anesthetic candidate with ASAI and ASAII grades and are satisfied with the patient's parents to participate in the study.The criteria for not attending the study include children under 6 years of age and over 12 years of age, underlying illness (inherited and genetic diseases, metabolic diseases, etc.), and parents' disagreement for participation in the study.

Intervention groups

Intervention group 1: Two minutes before anesthesia induction received 4 µg / kg of Intranasal remifentanil .Intervention group 2: Two minutes before anesthesia induction, 2 µg / kg intranasal Dexmedetomidine will receive .Control group: Two minutes before anesthesia induction, 1cc of intranasal normal saline will receive.

Main outcome variables

Hemodynamic change(systolic blood pressure; diastolic blood pressure; mean arterial blood pressure and heart rate)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N7**
Registration date: **2018-09-04, 1397/06/13**
Registration timing: **prospective**

Last update: **2018-09-04, 1397/06/13**
Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 2655

Email address

amir_shafa@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of intranasal dexmedetomidine and remifentanil on reduction of hemodynamic changes after intubation in children ages 6 to 12 years old under general anesthesia

Public title
Intranasal Dexmedetomidine and Remifentanil and hemodynamic changes after intubation in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: all children ages 6 to 12 years of age with general anesthetics, ASAI and ASAII grades, and consent from the parents of the patient to participate in the study.
Exclusion criteria:
The criteria for not attending the study include children under 6 years of age and over 12 years of age, underlying illness (inherited and genetic diseases, metabolic diseases, etc.), and parents' disagreement for participation in the study
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization based on random number tables
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications are prepared and encoded in syringes of equal volume, Drugs are prescribed by an anesthetist who is not known to the groups.The consequences of prescribing the drug are recorded by the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8185665843
Approval date
2017-09-02, 1396/06/11
Ethics committee reference number
ir.mui.rec.1396.3.091

Health conditions studied

1

Description of health condition studied
Hemodynamic and Respiratory complications after intubation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemodynamic change
Timepoint
One minute after the drug is given and one minute after the intubation
Method of measurement
Anesthetic monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Two minutes before anesthesia induction received 4 µg / kg of Intranasal remifentanil .Intervention group 2: Two minutes before anesthesia induction, 2 µg / kg intranasal Dexmedetomidine will receive .Control group: Two minutes before anesthesia induction, 1cc of intranasal normal saline will receive.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emamhossein hospital
Full name of responsible person
Amir Shafa
Street address
Emamhossein hospital,Emamkhomeini Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjoo
Street address
Isfahan University of Medical Sciences, Hezarjrib Ave
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81856665843
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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
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
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
The total data can be shared after Unidentifiable people
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Free access
Under which criteria data/document could be used
Accessible for everyone without a precondition
From where data/document is obtainable
Amir Shafa: shafa_amir@yahoo.com
What processes are involved for a request to access data/document
Request via email
Comments