Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Survey of effect of two single doses of bolus Dexmedetomidine (1 µg / kg and 2 µg / kg) on intraoperative hemodynamic status and agitation in the recovery of children undergoing Adenotonsillectomy;

Protocol summary

Study aim

1. Determination and comparison of mean arterial pressure before induction of anesthesia and every 15 minutes during surgery and recovery 2. Determination and comparison of mean heart rate before induction of anesthesia and every 15 minutes during surgery and recovery 3. Determination and comparison of mean SPO2 before induction of anesthesia and every 15 minutes during surgery and recovery 4. Determination and comparison of mean volume of bleeding during surgery based on CC 5. Determine and compare the average length of Intubation 6. Determine and compare the average length of stay in recovery 7. Determine and compare sedation score every 15 minutes 8. Determine and compare agitation score every 15 minutes 9. Determination and comparison of the average dose of propofol for the treatment of delirium

Design

Clinical trial with control group, with 3 parallel groups, double blind, randomized، sample size:105 people

Settings and conduct

The study is a double-blind randomized clinical trial conducted at Imam Hossein Children's Hospital in 1993-1999.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 3 to 10 years are candidates for ASAI, ASAII adenotonsillectomy and consent to participate in the study.Exclusion criteria: include any underlying disease , bleeding disorders, impaired coagulation tests and metabolic disorders

Intervention groups

three groups of 35 each: The first group received 1 µg / kg diluted dexmedetomidine in a volume of 10 ml slowly for ten minutes and the second group received 2 µg / kg diluted dexmedetomidine in a volume of 10 ml slowly for ten minutes and the third group received 10 ml of normal saline slowly. Within 10 minutes

Main outcome variables

Blood pressure, bradycardia, respiratory depression, Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046853N1**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Hasti sadat Aledavood

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey of effect of two single doses of bolus Dexmedetomidine (1 µg / kg and 2 µg / kg) on intraoperative hemodynamic status and agitation in the recovery of children undergoing Adenotonsillectomy;

Public title
Survey of effect of Dexmedetomidine on children undergoing Adenotonslectomy ;
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
3-10 year old childern candidates for adenotonsillectomy Children who fall into the ASAI, ASAII group in terms of physical condition to determine the risk of anesthesia Consent to participate in the study
Exclusion criteria:
Includes any underlying disease (heart-lung disease, kidney, glands, etc.) Bleeding disorders Impaired coagulation tests (PT, PTT, INR) Metabolic disorders (phenylketonuria, galactasomy, etc.).
Age
From **3 years** old to **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
First, 105 eligible patients are selected by simple random sampling, then to divide them into three groups, we use Random Allocation software, so that the code selected by this software for three groups of 35 people in 3 envelopes in packages A, B and C Each envelope will be assigned to one of the three groups by the person who is not involved in the process. For example, envelope A, which contains 35 random codes from 1001 to 1105, will be randomly assigned to one of the three intervention groups 1, or intervention 2, or control, and the syringes will be prepared according to the blinding conditions.
Blinding (investigator's opinion)
Double blinded
Blinding description
To meet the double blindness of the study, doses of both micrograms per kg and one micrograms per kg diluted Dexmedetomidine in a volume of 10 cc are embedded in the syringes. The other syringe will be made without dexmedetomidine and contains only 10 cc Normal saline. The specialist in these syringes will label the A, B and C labels and will provide the researcher daily. Thus, until the data is collected by the nurse, the registrant will not know the type of medication in the syringes. the information analyst will have no knowledge of the types of 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 of Medical Sciences
Street address
No.103, Padideh Bulding , Alvand 2 Ave., Ghadir Blvd.,Sepahan shar
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Province
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Postal code
8179914387
Approval date
2020-03-17, 1398/12/27
Ethics committee reference number
IR.MUI.MED.REC.1398.729

Health conditions studied

1

Description of health condition studied
Chronic tonsillitis and adenoiditis
ICD-10 code
J35.0
ICD-10 code description
Chronic tonsillitis and adenoiditis

Primary outcomes

1

Description
Agitation rate
Timepoint
Every 15 minutes in recovery
Method of measurement
Paediatric Anesthesia Emergence Delirium score

2

Description

Sedation rate

Timepoint

Every 15 minutes in recovery

Method of measurement

Ramsay Sedation Scale score

3

Description

Length of stay in recovery

Timepoint

Every 15 minutes in recovery

Method of measurement

Modified Aldrete Score

4

Description

Spo2

Timepoint

Before and during anesthesia Every 15 minutes in recovery

Method of measurement

by Pulse oximetr

5

Description

Blood pressure

Timepoint

Before and during anesthesia Every 15 minutes in recovery

Method of measurement

By manometer

6

Description

Heart rate

Timepoint

Before and during anesthesia Every 15 minutes in recovery

Method of measurement

manually

7

Description

Bleeding volume

Timepoint

During surgery

Method of measurement

In milliliter

8

Description

Average dose of propofol for the treatment of delirium

Timepoint

During recovery

Method of measurement

milligram per kilogram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : The first intervention group receives 1 micrograms per kilogram of dexmedetomidine manufactured by Elixir Company, which is diluted in a volume of 10 cc as a single dose and bolus and received within ten minutes. Dexmedetomidine with the formula C13H16N2 and with the brand name precedex is one of the Imidazole drugs that has Urinary excretion. It has a half-life of two to three hours and does not have active metabolites. It has a high protein binding (94%). This drug is a pure agonist or a complete alpha-2 receptor agonist. Various methods are used to maintain a stable hemodynamic status and reduce bleeding during surgery. On the other hand, prolonged surgery and instability of hemodynamics are associated with more complications of children's recovery Dexmedetomidine is a central alpha-2 adrenergic agonist that has both sedative and analgesic effects. The use of this drug in children has increased day by day due to its neuroprotective properties. According to the findings so far, dexmedetomidine is one of the few drugs that does not cause cognitive impairment in children after anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group :The second intervention group receives 2 micrograms per kilogram of dexmedetomidine manufactured by Elixir Company, which is diluted in a volume of 10 cc as a single dose and bolus and received within ten minutes.

Category

Treatment - Drugs

3

Description

Control group: 10 cc normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Hasti Aledavood

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr.Mozhgan Mortazavi (Vice-Chancellery for Research and Technology.)
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mortazavi@med.mui.ac.ir
Web page address
https://research.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
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Hasti sadat Aledavood
Position
Intern
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Other areas of specialty/work

Anesthesiology

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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

If necessary, the data can be published without name and with all the details.

When the data will become available and for how long

6 months after printing the results.

To whom data/document is available

Researchers working in popular scientific and academic centers who are employed and studying and have a relevant research in this field that needs my data to advance research.

Under which criteria data/document could be used

If the data of this study is needed to progress and conduct a similar study.

From where data/document is obtainable

The original authors of the study.

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

The researcher emails a valid letter from his / her work or employment stating the reason for the need for the data and after reviewing it in the research department and after the agreement of the authors and financial support centers, the data and documents are provided to them.

Comments