

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, ASAI 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 children candidates for adenotonsillectomy
Children who fall into the ASA I, ASA II 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

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No.103, Padideh Bulding , Alvand 2 Ave., Ghadir Blvd.,Sepahan shar

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Province

Isfahan

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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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
Hasti sadat Aledavood
Position
Intern
Latest degree
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Person responsible for updating data

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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

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