

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the effectiveness of Lidocaine and Dexmedetomidine on the severity of immediate complications after Tonsillectomy surgery

Protocol summary

Study aim

Investigating the effect of Lidocaine and Dexmedetomidine on the complications of Tonsillectomy

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 90 patients. Randomized in a simple way using a lottery.

Settings and conduct

This is a three-blind randomized clinical trial that will be conducted on 90 Tonsillectomy in Al-Zahra Hospital, Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are randomly assigned into groups, in each group the desired intervention is applied and the clinical symptoms of the patient are recorded. The researcher who records the patient's symptoms, the analysts who collect the data analyzed during the study, and the patients did not know the type of intervention applied in each group, so they were all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 4 to 12 years, class I and II ASA anesthesia, candidate for Tonsillectomy surgery, and consent to participate in the study. Exclusion criteria: the presence of acute respiratory infections, allergy to used drugs, abnormal coagulation tests

Intervention groups

10 minutes before anesthesia patients in Intervention group A: receive 1.5 mg/kg lidocaine 2% (manufactured by Aburihan company) intravenously within 10 minutes, followed by an intravenous infusion of 2% lidocaine in 20 ml of normal saline with a dose of 0.25 mg/kg/minute until the end of the operation. Intervention group B: receive 1 Mg/kg Dexmedetomidine (manufactured by Exir company), followed by an intravenous infusion of Dexmedetomidine in 20 ml of normal saline with a dose of 0.5Mg/kg/minute until the end of the operation and in Intervention group C: they receive 20 ml of normal saline as a bolus 10 minutes before anesthesia.

Main outcome variables

Bleeding rate, airway spasm, hoarseness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N49**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **prospective**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Lidocaine and Dexmedetomidine on the severity of immediate complications after Tonsillectomy surgery

Public title

Investigating the effect of Lidocaine and Dexmedetomidine on Tonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 4 to 12 years old Anesthesia class I and II according to ASA criteria Candidate for tonsillectomy surgery Informed consent to enter the study

Exclusion criteria:

The presence of acute respiratory infections Abnormal coagulation tests History of allergic to drugs used

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a simple randomized clinical trial in which patients enter the study groups by lottery; The medicines and placebo are placed in sealed, opaque, and similar form packets coded. Each code is also written on paper, folded, and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box; The pocket with the same number is the intervention that will apply to him. This process continues till the number of patients reaches the desired one.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a three-way blind clinical trial; In this way, the researcher who records the patient's symptoms is different from the person who prescribes the drug and has no knowledge of the type of drug and is blind. The analysts who analyze the data collected during the study also know the type of intervention. They don't have it in any group and they are blind. Even though the guardian of patients are included in the study, they do not know the type of intervention and are blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib

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Province

Isfahan

Postal code

8174673461

Approval date

2022-10-15, 1401/07/23

Ethics committee reference number

IR.MUI.MED.REC.1401.263

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

Tonsillectomy

ICD-10 code

J35.01

ICD-10 code description

Chronic tonsillitis

Primary outcomes**1****Description**

Bleeding rate

Timepoint

From the start of surgery to 6 hours after surgery

Method of measurement

Based on the examination of the number, weight and percentage of blood gases and the amount of blood in the suction device.

2**Description**

Laryngospasm

Timepoint

During the first two hours after the operation

Method of measurement

Based on the observation of signs of acute respiratory obstruction

3

Description

laryngitis

Timepoint

In the first 24 hours after the operation

Method of measurement

Based on the observation of hoarseness and snoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: patients 10 minutes before anesthesia, receive 1.5 mg/kg lidocaine 2% (manufactured by Aburihan company) intravenously within 10 minutes, followed by an intravenous infusion of 2% lidocaine in 20 ml of normal saline with a dose of 0.25 mg/kg/minute until the end of the operation. Then, sodium thiopental (manufactured by Elixir Company) amounting to 5 mg/kg, Cis-atracurium (manufactured by Iran Hormone Company) amounting to 0.15 mg/kg, and Fentanyl (Jahan Behold Company) amounting to 2 micrograms per kilogram of weight are used to induce anesthesia for all patients. For the continuation of anesthesia, isoflurane is used in the amount of MAC 1 (Minimum alveolar concentration). After induction of anesthesia, intubation will be done inside the chip with a tube without a cuff made by Supa company with a suitable diameter. At the end of the operation, neuromuscular blocks will be reversed with atropine (0.02 mg/kg) and neostigmine (0.04 mg/kg) and after waking up, all patients will be transferred to the post-anesthesia care unit (PACU). The patient's symptoms are measured and recorded from the beginning of anesthesia to 48 hours after recovery.

Category

Prevention

2

Description

Intervention group B: patients 10 minutes before anesthesia, receive 1 Mg/kg Dexmedetomidine (manufactured by Exir company), followed by an intravenous infusion of Dexmedetomidine in 20 ml of normal saline with a dose of 0.5Mg/kg/minute until the end of the operation. Then, sodium thiopental (manufactured by Elixir Company) amounting to 5 mg/kg, Cis-atracurium (manufactured by Iran Hormone Company) amounting to 0.15 mg/kg, and Fentanyl (Jahan Behold Company) amounting to 2 micrograms per kilogram of weight are used to induce anesthesia for all patients. For the continuation of anesthesia, isoflurane is used in the amount of MAC 1 (Minimum alveolar concentration). After induction of anesthesia, intubation will be done inside the chip with a tube without a cuff made by Supa company with a suitable diameter. At the

end of the operation, neuromuscular blocks will be reversed with atropine (0.02 mg/kg) and neostigmine (0.04 mg/kg) and after waking up, all patients will be transferred to the post-anesthesia care unit (PACU). The patient's symptoms are measured and recorded from the beginning of anesthesia to 48 hours after recovery.

Category

Prevention

3

Description

Control group C: patients 10 minutes before anesthesia, receive 20 ml of normal saline as a bolus. Then, sodium thiopental (manufactured by Elixir Company) amounting to 5 mg/kg, Cis-atracurium (manufactured by Iran Hormone Company) amounting to 0.15 mg/kg, and Fentanyl (Jahan Behold Company) amounting to 2 micrograms per kilogram of weight are used to induce anesthesia for all patients. For the continuation of anesthesia, isoflurane is used in the amount of MAC 1 (Minimum alveolar concentration). After induction of anesthesia, intubation will be done inside the chip with a tube without a cuff made by Supa company with a suitable diameter. At the end of the operation, neuromuscular blocks will be reversed with atropine (0.02 mg/kg) and neostigmine (0.04 mg/kg) and after waking up, all patients will be transferred to the post-anesthesia care unit (PACU). The patient's symptoms are measured and recorded from the beginning of anesthesia to 48 hours after recovery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Shima Shams

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor assistant of Anesthesia and Intensive care

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available