Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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

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Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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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
Isfehan

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: patients10 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
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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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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