

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of intraoperative lidocaine-epinephrine administration on complications after tonsillectomy

Protocol summary

Study aim

The effect of intraoperative lidocaine-epinephrine administration on complications after tonsillectomy

Design

A randomized double-blind clinical trial with a control group with parallel groups, phase 3 on 110 patients, Permuted block randomization.

Settings and conduct

This study will be performed to evaluate the effect of lidocaine-epinephrine administration in reducing complications after tonsillectomy in patients referred to Kowsar Hospital in Sanandaj. In this study, in the intervention group, lidocaine impregnated with epinephrine was injected into the tonsil bed during the operation and its effects on reducing complications such as pain and bleeding after the operation were evaluated. In this double-blind study, patients and nurses evaluating the conditions and complications in patients are not aware of grouping.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Informed consent of the patient or parents. 2. Intravenous anesthesia induction planning. 3. Being in Status 1 or 2 ASA classification. Exclusion Criteria: 1. Sensitivity to local anesthetics. 2. History of cardiovascular disease. 3. Occurrence of life-threatening conditions such as cardiopulmonary arrest. 4. History of mental and psychological disease

Intervention groups

Intervention group: In this group of patients, lidocaine 1% and epinephrine 1/100,000 are administered in the tonsils bed. control group: This group of patients does not have any intervention compared to the usual surgical conditions.

Main outcome variables

1. Pain 2. Bleeding 3. Length of hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210314050703N1**

Registration date: **2021-04-02, 1400/01/13**

Registration timing: **prospective**

Last update: **2021-04-02, 1400/01/13**

Update count: **0**

Registration date

2021-04-02, 1400/01/13

Registrant information

Name

Negin Ghadami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 8519

Email address

ghadaminegin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intraoperative lidocaine-epinephrine administration on complications after tonsillectomy

Public title

The effect of intraoperative lidocaine-epinephrine administration on complications after tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent of the patient or parents Intravenous anesthesia induction planning Being in Status 1 or 2 ASA classification

Exclusion criteria:

Sensitivity to local anesthetics History of cardiovascular disease History of mental and psychological disease Occurrence of life-threatening conditions such as cardiopulmonary arrest

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization. In this method, in each block, 2 patients are randomly identified by assigning codes A or B and based on the assigned code, are placed in the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study do not know which control and intervention groups they belong to. Also, the patient evaluating nurse is not aware of the grouping of patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pardsi of Kurdistan University of Medical Sciences,

Pasdaran Blvd.

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2019-12-24, 1398/10/03

Ethics committee reference number

IR.MUK.REC.1398.227

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

Hypertrophy of tonsils

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

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

Pain

Timepoint

30 and 60 minutes after the end of surgery.

Method of measurement

Visual Analogue Scale

2**Description**

Bleeding

Timepoint

During surgery and 6, 12 and 24 hours after surgery.

Method of measurement

Based on the number of sterile gases impregnated with blood (each small sterile gas absorbs 4 to 5 ml and each large gas absorbs up to 20 ml).

3**Description**

Length of Hospitalization

Timepoint

After patients discharge.

Method of measurement

Based on the day of hospitalization.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of lidocaine 1% - epinephrine 1 in 100,000 in the tonsil bed before surgery. In this group, before starting the surgical procedure, the surgeon injects 4 ml of 1% lidocaine, which is in a syringe soaked in epinephrine 1 in 100,000, into the tonsil bed.

Category

Treatment - Drugs

2

Description

Control group: No intervention is performed and surgery is performed as usual.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital.

Full name of responsible person

Negin Ghadami

Street address

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Web page address

<http://muk.ac.ir/Page?pagelD=14>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Negin Ghadami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Specialist

Latest degree

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data on the main consequences will be shared.

When the data will become available and for how long

12 Months.

To whom data/document is available

Academic Researchers.

Under which criteria data/document could be used

Meta-Analysis is allowed.

From where data/document is obtainable

Dr. Negin Ghadami

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

Email to: ghadaminegin@gmail.com

Comments