

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of lidocaine- paracetamol with lidocaine- ketamine on post-tonsillectomy pain relief in children

Protocol summary

Study aim

Comparison of the effect of lidocaine- paracetamol with lidocaine- ketamine on post-tonsillectomy pain relief in children

Design

This study will be done in the operating room. All of the drugs solution of this study will be prepared by only one person who is aware of the study's grouping, in the Similar syringes 10 cc. Anesthesiologist, patients, and all medical staff that will collaborate in the study will not aware of the drug allocated to each patient.

Settings and conduct

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 114 patients who will be undergoing open tonsillectomy will be enrolled. Eligible patients will be randomly allocated into 3 equal A, B and C groups by block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA grade I or II (American Society of Anesthesiology classification), Patients between 3 and 10 years old and Patients undergoing open tonsillectomy. Exclusion criteria: Allergy to the drugs used in the study, Positive history of Heart, kidney diseases and chronic pain and Lack of parental consent.

Intervention groups

Intervention group(A): ampoule of lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus Paracetamol 15 mg/kg . This solution will be injected to the patient 15 minutes before the surgery Intervention group(B): ampoule of Lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus 0.25 mg/kg of ketamine. This solution will be injected to the patient 15 minutes before the surgery Control group(C): ampoule of lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus normal saline (with the same volume of the studied drugs) is prepared as a placebo. This solution will be injected to the patient 15 minutes before the surgery.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056627N2**

Registration date: **2024-09-18, 1403/06/28**

Registration timing: **prospective**

Last update: **2024-09-18, 1403/06/28**

Update count: **0**

Registration date

2024-09-18, 1403/06/28

Registrant information

Name

Zeinabsadat Fattahi Saravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

zefattahi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-01, 1403/07/10

Expected recruitment end date

2025-08-01, 1404/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of lidocaine- paracetamol with lidocaine- ketamine on post-tonsillectomy pain relief in children

Public title

Comparison of the effect of lidocaine- paracetamol with lidocaine- ketamine on post-tonsillectomy pain relief in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ASA grade I or II (American Society of Anesthesiology classification) Patients between 3 and 10 years old Patients undergoing open tonsillectomy

Exclusion criteria:

Allergy to the drugs used in the study significant cognitive impairment in children Positive history of Heart, kidney diseases and chronic pain. Lack of parental consent

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into three groups by block randomization. In this technique, a permutation block of size 6 will be made for patients of three groups A, B and C. In each block, equal numbers for three groups will be considered in alternative positions. Then 19 blocks of size 6 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs are provided in the form of similar 10 cc syringes by the first person, these drugs, which have the same color and size and in similar colors, are injected by the second person who is completely unaware of the contents of the syringes. The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz Medical School.

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

197871345

Approval date

2024-03-05, 1402/12/15

Ethics committee reference number

IR.SUMS.MED.REC.1403.036

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**

Pain after surgery

Timepoint

15, 30 and 45 minutes after surgery in recovery.

Method of measurement

Wong-Baker Pain Scale.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group(A): After selection of target group,

ampoule of lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus Paracetamol 15 mg/kg .This solution will be injected intravenously to the patient 15 minutes before the start of surgery by angioket number (22-24).

Category

Treatment - Drugs

2**Description**

Intervention group(B): After selection of target group, ampoule of Lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus 0.25 mg/kg of ketamine . This solution will be injected intravenously to the patient 15 minutes before the start of surgery by angioket number (22-24).

Category

Treatment - Drugs

3**Description**

Control group: After selection of target group, ampoule of lidocaine with a dose of 1 mg/kg will be prepared as Similar syringes 10 cc plus normal saline (with the same volume of the studied drugs) is prepared as a placebo. This solution will be injected intravenously to the patient 15 minutes before the start of surgery by angioket number (22-24).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Dastgheib Hospital

Full name of responsible person

Mahsa, Jalilpour aghdam

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Hafez St, Shiraz.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

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7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa Jalilpoura gdam

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available