Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 undergo 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)
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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

Street address
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
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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

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Person responsible for updating data

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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