Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of the effect of peritonsillar injection of ketamine and lidocaine before tonsillectomy on pain after surgery

Protocol summary

Study aim
Determining and comparing the effect of peritonsillar injection of ketamine and lidocaine to patients before tonsillectomy on pain reduction in patients after surgery.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized block, on 90 patients in 3 groups of 30

Settings and conduct
After performing intubation and anesthesia before surgical incision, peritonsillar injection of 2 ml of ketamine and lidocaine (ketamine and lidocaine will be diluted in 2 ml syringes) respectively in the control group, k and l with one technique and as Blowing from the upper and lower poles of the tonsils by an injection surgeon and 5 minutes later the surgery will start. Blood pressure, heart rate (systolic and diastolic) and SpO2 will be recorded every ten minutes during surgery. The duration of anesthesia and operation is also recorded by the anesthesia assistant.

Participants/Inclusion and exclusion criteria
Entry criteria include: patients in classes I and II in the ASA physical status classification system based on the anesthesiologist's diagnosis. 1. The age of entering the study is 3 to 30 years. 2- Absence of metabolic and endocrine diseases. 3- No history of psychotic diseases. 4- Speaking ability in adults. 5- Absence of physical and mental disorders in children. Exclusion criteria include: 1- Allergy to injectable drugs. 2- Postoperative hemodynamic disorders. 3- Lack of satisfaction and cooperation after the operation. 4- It will be receiving housing.

Intervention groups
30 patients in group C (control), 30 patients in group k (receiver of ketamine) and 30 patients in group l (receiver of lidocaine) will be randomized.

Main outcome variables
How effective are ketamine and lidocaine on postoperative pain?

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230208057353N1**
Registration date: **2023-03-06, 1401/12/15**
Registration timing: **prospective**

Last update: **2023-03-06, 1401/12/15**
Update count: **0**

Registration date
2023-03-06, 1401/12/15

Registrant information

Name
Mahdi Asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3858 5462

Email address
mahdiasadi1581376@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-21, 1402/01/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

comparison of the effect of peritonsillar injection of ketamine and lidocaine before tonsillectomy on pain after surgery

Public title
comparison of ketamine and lidocaine in tonsilectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age of entering the study is 3 to 30 years Absence of metabolic and endocrine diseases No history of psychosis Speech ability in adults Absence of physical and mental disorders in children
Exclusion criteria:
Allergy to injectable drugs Postoperative hemodynamic disorders Lack of satisfaction and cooperation after the operation Analgesics
Age
From **3 years** old to **30 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block randomization: Randomization tool: website https://www.sealedenvelope.com/ How to make a random sequence: To perform this method at the beginning in the mentioned site, the number of intervention groups (three groups C, k and l), the volume of each block (blocks of 6) and the number of sample size (90 people) were entered. Then the site presented a list with 15 blocks of 6. In this study, we use blocks of 6, and the website performs randomization and assigns numbers to the blocks. Allocation concealment method: sealed envelopes
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients, the otolaryngologist who performs the surgery, the anesthesiologist who prescribes the anesthetic, and the anesthesiologist (MSc) who records the level of pain and restlessness, from the postoperative results of assigning the patients to two They do not know the group or drug used. The data analyst will also be unaware of which patient is ketamine, which is lidocaine, and which is part of the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Zirtol.Daneshgah Ave
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591938839
Approval date
2023-01-29, 1401/11/09
Ethics committee reference number
IR.YUMS.REC.1401.166

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
minute 30-60-90 after surgery
Method of measurement
Visual Analog Scale and Numeric Pain Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: receiving ketamine. After intubation and anesthesia before surgical incision, peritonsillar injection of 2 ml of ketamine (ketamine will be diluted in 2 ml syringes) with a technique and as a fan from the upper poles. and below the tonsils by an injection surgeon and 5 minutes later the operation will

begin. Blood pressure, heart rate (systolic and diastolic) and SpO2 will be recorded every ten minutes during surgery. The duration of anesthesia and operation is also recorded by the anesthesia assistant.

Category

Treatment - Drugs

2

Description

The second intervention group: receiving lidocaine. After intubation and anesthesia before surgical incision, peritonsillar injection of 2 ml of lidocaine (lidocaine will be diluted in 2 ml syringes) with a technique and as a fan from the upper poles. and below the tonsils by an injection surgeon and 5 minutes later the operation will begin. Blood pressure, heart rate (systolic and diastolic) and SpO2 will be recorded every ten minutes during surgery. The duration of anesthesia and operation is also recorded by the anesthesia assistant.

Category

Treatment - Drugs

3

Description

Control group: Control group: In this group, no action will be taken by the researcher and only their demographic information will be collected.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Sajad hospital
Full name of responsible person
Mahdi Asadi
Street address
Next to Azadi Hotel
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Amirhosein Doosti Motlagh
Street address
Zirtel.University St. at the end of the street
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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Mahdi Asadi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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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