

# 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)

##### Phone

+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 tonsillectomy

#### 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 I), 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-Boyerahmad

###### 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**

Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591938839

**Phone**

+98 74 3322 0166

**Email**

mahdiasadi1581376@gmail.com

**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

**City**

Yasuj

**Province**

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**Phone**

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**Email**

mahdiasadi1581376@gmail.com

**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 scientific 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**

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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

**Person responsible for updating data****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