

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of peritonsillar infiltration of ketamin and lidocaïen for post operative pain relief in children following tonsillectomy

Protocol summary

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Summary

This Randomized Clinical Trail (RCT) study investigates the effects of injection of Ketamine and Lidocaine prior to surgery in reducing pain of post surgery of tonsillectomy. The participants are candidates of tonsillectomy, referring to Emam Khomeini Hospital of Ardabil. The participants will be randomly assigned into one of following three groups to receive either an injection of 1 mg/kg Ketamine or Lidocaine in the intervention group and the same amount of normal saline in the control group. The intensity of pain and comfort will be evaluated with Chops' test and Wilson's test respectively, and Ocher pain will be evaluated by an anesthesiologist.

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2010-04-20, 1389/01/31

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903044027N1**

Registration date: **2010-09-30, 1389/07/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Akbar Pirzadeh

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 0060

Email address

Scientific title

Effect of peritonsillar infiltration of ketamin and lidocaïen for post operative pain relief in children following tonsillectomy

Public title

Effect of peritonsillar infiltration of ketamin and lidocaïen for post operative pain relief in children following tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: large tonsil, age between 3 and 15 year Exclusion criteria: Systematic diseases, hematologic diseases

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Ardabil

City

Ardabil

Postal code

Approval date

empty

Ethics committee reference number

6-7

Health conditions studied

1

Description of health condition studied

Tonsillar hypertrophy

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes

1

Description

Pain

Timepoint

15 and 30 minutes and 1, 2, 4, 6, 8, 16, and 24 hours postoperation

Method of measurement

Vilson and Choobs test

Secondary outcomes

empty

Intervention groups

1

Description

Under general anesthesia five minutes before surgery 0.1 mg/kg lidocain will be injected into peritonsillar area

Category

Treatment - Drugs

2

Description

Under general anesthesia five minutes before surgery 0.1 mg/kg ketamin will be injected into peritonsillar area

Category

Treatment - Drugs

3

Description

Under general anesthesia five minutes before surgery 2 cc water [control] will be injected into peritonsillar area

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil University of Medical Sciences

Full name of responsible person

Akbar Pirzadeh

Street address

Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Mirzarahimi

Street address

Ardabil University of Medical Sciences

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Postal code****Phone**

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Full name of responsible person

Akbar Pirzadeh

Position

Otolaryngologist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*