

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of topical injection of tramadol, ketamine and lidocaine on post-tonsillectomy pain, nausea and vomiting

Protocol summary

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Summary

aim of the study:show the effect of topical injection of tramadol, ketamine and lidocaine on post-tonsillectomy pain , nausea and vomiting the study is a double blind clinical trial carried out on 60 elective tonsillectomy patients in Imam Khomeini Hospital, Ahwaz, in 2014.inclusin criteria is patient with chronic tonsillitis and exclusion criteria is patients with any underlying disease, with drug reaction history, and whom the surgery time is more than one hour. The patients randomly divide into four groups ; tramadol, lidocaiene ketamin, placebo post operation pain and nausea and vomiting record by an ENT resident whom does not know about groups.

Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapor University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520320N1**

Registration date: **2015-04-10, 1394/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-10, 1394/01/21

Registrant information

Name

Somayeh Araghi

Name of organization / entity

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Country

Iran (Islamic Republic of)

Phone

+98 61 3333 9664

Email address

Scientific title

Comparison of the effect of topical injection of tramadol, ketamine and lidocaine on post-tonsillectomy pain, nausea and vomiting

Public title

The effect of topical injection of tramadol, ketamine and lidocaine on post-tonsillectomy pain, nausea and vomiting

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: patient with chronic tonsillitis exclusion criteria: patients with any underlying disease, with drug reaction history, and whom the surgery time is more than one hour

Age

From **4 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Ethics Committee of Jondishapour Ahvaz University of Medical Sciences

Street address

Jondishapour Ahvaz University of Medical Sciences, Golestan

City

Ahvaz

Postal code

Approval date

2015-01-03, 1393/10/13

Ethics committee reference number

Ajums.rec.1393.346

Health conditions studied

1

Description of health condition studied

chronic tonsillitis, tonsils and adenoids hypertrophy

ICD-10 code

J35

ICD-10 code description

Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description

pain

Timepoint

1,4,8,16,24 hour post-operation

Method of measurement

faces pain scale

2

Description

nausea

Timepoint

1,4,8,16,24 hour post-operation

Method of measurement

4 option scale: none,mild, moderate, sever

3

Description

vomiting

Timepoint

1,4,8,16,24 hour post-operation

Method of measurement

none,mild(1 episode),moderate(2-3), severe(>3 episode)

Secondary outcomes

1

Description

surgery time

Timepoint

start and finish time of surgery

Method of measurement

minutes

Intervention groups

1

Description

Intervention group 1: Ketamin 0.5 mg/kg 2cc total, 1cc injection before operation in each tonsillar bed

Category

Treatment - Drugs

2

Description

Intervention group 2: tramadol 2 mg/kg Daroupakhsh, Iran 2cc total, 1cc injection before operation in each tonsillar bed

Category

Treatment - Drugs

3

Description

Intervention group 3: lidicaine hydrochloride 20 mg/ml +epinephrine 0.00125% 2cc total, 1cc injection before operation in each tonsillar bed

Category

Treatment - Drugs

4

Description

Control goup: saline 2 cc, 1cc in each tonsilar bed

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Somayeh Araghi

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

ENT Department, Imam Khomeini Hospital , 24 Metri Avenue, Ahavz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Ahvaz Jondishapour 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

Person responsible for general inquiries

Contact

Name of organization / entity

Jondishapour Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Somaye Araghi

Position

Resident

Other areas of specialty/work

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Web page address

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