# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison the effect of topical ketamine,morphine and lidocaine spray on post operative pain in tonsillectomy

## Protocol summary

**Summary**

The purpose of this study is to investigate the effecacy of local ketamine, Morphin, and Lidocaine spray for controlling pain after tonsillectomy in children; in this clinical trial, 124 children with the age of 3-12 who selected for tonsillectomy will be divided to four group ; Ketamine group (k), Morphin group (M), Lidocain group (L), and Control group (C). The premedication, induction and maintenance of anesthesia in all of patient will be similar. At the end of surgery 0.5 mg/kg ketamine's spray in group (k), 0.05 mg/kg morphin's spray in group (M), 2 mg/kg lidocaine's spray in group (L), and normal saline spray in group C (8 puffs) will be used on the surface of surgery zone. After ex tubation and the entrance of patient to recovery room, pain scaling will be assessed for 1 hour (with 20 minute intervals) by personnel who were not aware of research methods. Pain control will be scaled with FLACC Pain Scaling System. In this system if anyone of patient in recovery room complained for severe pain, score 6 and more, will received pethidine 0.5 mg/kg for relief.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201104236256N1**
Registration date: **2011-06-18, 1390/03/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-06-18, 1390/03/28

**Registrant information**

**Name**

Sevak Hatamian

**Name of organization / entity**

Qazvin university of medical sciences and health servics

**Country**

Iran (Islamic Republic of)

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+98 28 1223 6381

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice-chancellorfor research, Qazvin University of Medical Sciences

**Expected recruitment start date**

2010-06-22, 1389/04/01

**Expected recruitment end date**

2010-08-29, 1389/06/07

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of topical ketamine,morphine and lidocaine spray on post operative pain in tonsillectomy

**Public title**

Comparison the effect of topical ketamine,morphine and lidocaine spray on post operative pain in tonsillectomy

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion: Elective tonsillectomy surgery; age between 3-12 years; did not use anti convulsive, antiinflamatory or analgesic agents; negative history of hypersensitive reactions to morphine or lidocaine or hyperactive airway disease such asthma and testimonial form patients

Exclusion : using anti convulsive, antiinflamatory or analgesic agents; history of hypersensitive reactions to morphine or lidocaine or hyperactive airway disease such asthma

**Age**
From **3 years** old to **12 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **124**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Qazvin University of Medical Sciences Ethics committee

**Street address**
Shahid Bahonar Blvd.

**City**
Qazvin

**Postal code**

**Approval date**
2010-06-07, 1389/03/17

**Ethics committee reference number**
4350/20/28

## Health conditions studied

**1**

**Description of health condition studied**
Hypertrophy of tonsils

**ICD-10 code**
J35.1

**ICD-10 code description**
Hypertrophy of tonsils

## Primary outcomes

**1**

**Description**
Pain

**Timepoint**
During 20 Min

**Method of measurement**
FLACC (the face, legs, activity, cry and consolability)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention:lidocain spray 10%(100mg/ml) with dose 2mg/kg

**Category**
Prevention

**2**

**Description**
Control : normal saline spray

**Category**
Prevention

**3**

**Description**
Intervention:ketamine spray 1%(10mg/ml)with dose 0.5mg/kg

**Category**
Prevention

**4**

**Description**
Intervention:morphin spray 0.1%(1mg/ml)with dose 0.05% mg/kg

**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Shid Rajee Hospital

**Full name of responsible person**
Dr Sevak Hatamian

**Street address**
Padeghan Street

**City**
Qazvin

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Qazvin University of Medical Sciences
**Full name of responsible person**
Dr Saeed Assefzadeh
**Street address**
Shahid bahonar Blvd
**City**
Qazvin
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Qazvin 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**
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Qazvin University of Medical Sciences
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Resident Anesthasia
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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)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*