

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 efficacy of local ketamine, Morphine, 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 groups; Ketamine group (K), Morphine group (M), Lidocaine group (L), and Control group (C). The premedication, induction and maintenance of anesthesia in all of patients will be similar. At the end of surgery 0.5 mg/kg ketamine's spray in group (K), 0.05 mg/kg morphine'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 extubation 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 receive 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 services

Country

Iran (Islamic Republic of)

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+98 28 1223 6381

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for 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, antiinflammatory or analgesic agents; negative history of hypersensitive reactions to morphine or lidocaine or hyperactive airway disease such as asthma and testimonial from patients

Exclusion : using anti convulsive, antiinflammatory or analgesic agents; history of hypersensitive reactions to morphine or lidocaine or hyperactive airway disease such as 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**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr Sevak Hatamian

Position

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Postal code**Phone****Fax****Email****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