Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Lidocaine-Morphine and Lidocaine-Ketamine Spray on Post-Tonsillectomy Pain in Children

Protocol summary

Summary

Objectives: Tonsillectomy is one of the most common pediatric surgeries and post-operation pain is an important complication of this surgery. The aim of this study is to compare the effect of Lidocaine-Morphine and Lidocaine-Ketamine spray on post-tonsillectomy pain in children. Design: In this clinical trial, 120 children who are candidate for elective tonsillectomy will be randomly divided into one of the three groups of Lidocaine-Morphine or Lidocaine–Ketamine or control (placebo) (each group has 40 participants). Setting and conduct: After induction of general anesthesia and intubation, the operation will be performed (the same rule for all patients). At the end of surgery, we use handmade Lidocaine-Morphine spray for Lidocaine-Morphine group, handmade Lidocaine–Ketamine spray for Lidocaine–Ketamine group and handmade normal saline spray as placebo for control group (locally at the operation site). After extubation when patients enter the recovery ward, until one hour, their pain will be assessed subjectively by an unaware person with FLACC Pain Scaling System. In the case of more than 4 scores for post-operation pain, one dose of Petedine (0/5 mg/kg) will be injected intravenously. Major Inclusion and Exclusion criteria: 6 to 12 years old children who are candidate for elective tonsillectomy without history of asthma or allergy to morphine or lidocaine or recent usage of analgesics. Intervention: Usage of Lidocaine-Morphine spray, Lidocaine–Ketamine spray or normal saline spray. Main outcome measures (variables): Finally the scores of pain of all groups' participants will be compared to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111019037N4**

Registration date: **2014-11-17, 1393/08/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-17, 1393/08/26

Registrant information

Name

Mahdieh Yousef-Zanjani

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Lidocaine-Morphine and Lidocaine-Ketamine Spray on Post-Tonsillectomy Pain in Children

Public title

Comparison of the Effect of Lidocaine-Morphine and Lidocaine-Ketamine Spray on Post-Tonsillectomy Pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: 6 to 12 years old children who are candidate for elective tonsillectomy. Exclusion criteria: Patients who usually use anticonvulsants or analgesics or anti-inflammatory agents; patients with history of allergy to morphine or lidocaine; patients with underline diseases like asthma.

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The children who enter this trial will be randomly selected for each groups by colored cards.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin university of medical sciences

Street address
Shahid Bahonar Boulevard

City
Qazvin

Postal code

Approval date
2014-06-12, 1393/03/22

Ethics committee reference number
28.20.8849

Health conditions studied

1

Description of health condition studied
Pain in throat (surgery site)

ICD-10 code
R07.0

ICD-10 code description
Pain in throat

Primary outcomes

1

Description
Post-operation pain

Timepoint
From the enterance to the recovery ward until one hour (every 20 minutes)

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Local usage of handmade Lidocaine-Morphine spray (including Lidocaine 10% spray from Irandarou manufacturing company, Tehran, Iran, registered No. 1228129223 and Morphine 10mg/ml ampule from Daroupakhsh manufacturing company, Tehran, Iran, registered No. 1228081477): 1puff/8kg on tonsillectomy site. Each puff: 0.1mg Lidocaine + 0.05mg Morphine.

Category
Treatment - Drugs

2

Description
Second intervention group: Local usage of handmade Lidocaine-Ketamine spray (including Lidocaine 10% spray from Irandarou manufacturing company, Tehran, Iran, registered No. 1228129223 and Ketamine 50mg/ml ampule from Rotexmedica manufacturing company, Germany, registered No. 1228070822): 1puff/8kg on tonsillectomy site. Each puff: 0.1mg Lidocaine + 0.05mg Ketamine.

Category
Treatment - Drugs

3

Description
Third intervention group: Local usage of handmade normal saline spray (including normal saline solution 9mg/ml from Daroupakhsh drug manufacturing company, Tehran, Iran, registered No. 1228057458): 1puff/8kg on tonsillectomy site.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods Pediatrics Hspital
Full name of responsible person
Dr. Abbas Hosseini-Jahromi
Street address
Qods Square
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Dr. Ardalan Samadzadegan
Street address
Qods Pediatrics Hspital
City
Qazvin
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Ardalan Samadzadegan
Position
Anesthesiology
Other areas of specialty/work
Street address
Qods Pediatrics Hospital, Qods Square
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Postal code
Phone
00
Fax
Email
yusefi.mahdieh@yahoo.com
Web page address

Person responsible for updating data

Contact

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