Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Preemptive peritonsillar infiltration with bupivacaine in combination with tramadol improves pediatric posttonsillectomy pain better than using bupivacaine or tramadol alone: A randomized, placebo-controlled, double blind clinical trial

Protocol summary

Summary

Post tonsillectomy pain is one of most common problem after anesthesia, therefore use of a good anesthesia technique with minimum side effect is a important aim. This study was performed to compare the efficacy of peritonsillar infiltration of bupivacaine, tramadol and combination of bupivacaine-tramadol in post tonsillectomy pain. Methods: in a double blind trial، 120 ASA I & II childeren condidated for tonsillectomy were randomized into 4 groups: Peritonsillar infiltration with bupivacaine 1mg/kg in Group 1, tramadol 2mg/kg in Group 2, combination of bupivacaine- tramadol in Group 3 and saline in Group 4 was done and post surgical pain were recorded subjective in each person.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308035362N8**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

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Mohammadreza Safavi
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preemptive peritonsillar infiltration with bupivacaine in combination with tramadol improves pediatric posttonsillectomy pain better than using bupivacaine or tramadol alone: A randomized, placebo-controlled, double blind clinical trial

Public title

Efficacy of local anaesthesia of bupivacaine in combination with tramadol in post adenotonsillectomy pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 5 to 15 years old who were candidate for tonsillectomy with or without adenoidectomy;

exclusion criteria: patients with acute pharyngeal infection; allergy to bupivacaine or tramadol; acute and active infection of respiratory tract with fever and rhonchi; constant use of sedative or analgesic hypnotic; peritonsillar abscess; renal disease; liver disease; asthma and coagulation disorders.

Age
From **5 years** old to **15 years** old

Gender
Both

Phase
N/A

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
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan

City
Isfahan

Postal code
8174675731

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
388526

Health conditions studied

1

Description of health condition studied
Local anaesthetics

ICD-10 code
Y48.3

ICD-10 code description
Local anaesthetics

2

Description of health condition studied
Acute pain

ICD-10 code
R52.0

ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain

Timepoint
Time of 0,15,30,60 minutes in recovery and 4,8,16,28 hour in ward

Method of measurement
ops (objective pain scale)

Secondary outcomes

1

Description
Consciousness level

Timepoint
Time of 0,15,30,60 minutes in recovery and 4,8,16,24 hours in ward

Method of measurement
Watching in 4 grading

2

Description
Mean blood pressure - mean heart rate

Timepoint
Time of 0,10,30,60 minutes in operation and 0,30,60 minutes in recovery

Method of measurement
Monitoring

3

Description
Nausea and vomiting

Timepoint
After operation to 24 hours

Method of measurement
Watching

4

Description
Mean time to awaking

Timepoint
after operation

Method of measurement
Watching

5

Description
Mean first time to asking analgesic
Timepoint
After operation to 24 hours
Method of measurement
Watching

6

Description
Mean time to extubation
Timepoint
after operation
Method of measurement
Watching

Intervention groups

1

Description
Received peritonsillar injection of bupivacaine 0.5% (1mg/kg) in adrenalin 1:200000 in a volume of 3 cc with normal saline (N/S) before surgical insicion
Category
Prevention

2

Description
Received peritonsillar infiltration of tramadol 2mg/kg in adrenalin 1:200000 in a volume of 3 cc with normal saline (N/S) before surgical insicion
Category
Prevention

3

Description
Received peritonsillar infiltration of tramadol 2 mg/kg and bupivacaine 1mg/kg in adrenalin 1:200000 in a volume of 3 cc before surgical insicion
Category
Prevention

4

Description
Received peritonsillar infiltration of N/S in a volume of 3 cc before surgical insicion
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Dr. Mohammadreza Safavi
Street address
Kashani street
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Azim Honarmand
Street address
Kashani street
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
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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