

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 childrenen 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

Name

Mohammadreza Safavi

Name of organization / entity

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Isfahan University of Medical Sciences, Isfahan

Country

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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 incision

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 incision

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 incision

Category

Prevention

4

Description

Received peritonsillar infiltration of N/S in a volume of 3 cc before surgical incision

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

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Safavi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

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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