# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**
**Name**
Mohammadreza Safavi
**Name of organization / entity**
Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan
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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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## 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*