

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effects of peritonsillar injection of ketamine with tramadol on the post tonsillectomy pain

#### Protocol summary

##### Summary

Post tonsillectomy pain management in children remains a problem. Peritonsillar infiltration with tramadol or ketamine (either alone) reported had effective analgesic in other studies. The purpose of this study is to determine which of two drugs is better to pain reduction with less side effects. This randomized double-blinded placebo-controlled clinical trial study perform on 126 patients 5-12 yeas in ASA class I-II, who are candidate for elective bilateral tonsillectomy due to chronic or recurrent tonsillitis. Patients don't have any past history of coexisting disease. After anesthesia induction and tracheal intubation, patients randomly allocate to receive tramadol 2 mg/kg (n = 42) or ketamine 0.5 mg/kg (n=42) or normal saline (n=42) in volumes of 2cc, bilateral peritonsillar injection (each side 1 cc) 3 min before surgery. Anesthesia method and surgical technique are same for all patients. Patients don't have post history of coexisting disease. If we have any unexpected problems during study (excessive bleeding, difficult intubation,...), patient is excluded of study. After end of surgery and extubation, pain with CHEOPS score is assessed in the recovery room at 10- 20- 30- 40- 60 min post surgery and then in the ward at 2- 4- 6- 8- 12 hours. Finally we analyze the collected data with using statistical software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103255764N2**

Registration date: **2011-04-25, 1390/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-04-25, 1390/02/05

##### Registrant information

###### Name

Vida Ayatollahi

###### Name of organization / entity

Shahid Sadughi University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 1821 5730

###### Email address

ayatt.vida@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of Shahid Sadughi Medical University

##### Expected recruitment start date

2010-05-31, 1389/03/10

##### Expected recruitment end date

2010-11-11, 1389/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of peritonsillar injection of ketamine with tramadol on the post tonsillectomy pain

##### Public title

The effects of peritonsillar injection of ketamine or tramadol on the post tonsillectomy pain

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 1); 5-12 yr patients, who are candidate

for elective bilateral tonsillectomy due to chronic or recurrent tonsillitis ; 2);ASA class =I,II (American society of anesthesiology); 3) ;No evidence of difficult air way management: 4);Without cardio, pulmonary, endocrine, psycho and metabolic disease; 5);Do not use analgesic drugs in the last 24 hours; 6);No electrolyte abnormalities; 7);No tonsillectomy indication except chronic or recurrent tonsillitis; 8);No mental, cerebral and growth problems; 9);No sore throat Exclusion criteria: 1) ;surgery time > 1 hour; 2) ;History of reaction to drugs studies; 3) ;Unexpected problems during anesthesia and surgery (excessive bleeding, difficult intubation,...); 4) ;Cauterization that used during surgery

#### Age

From **5 years** old to **12 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **126**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Medical Sciences and Health Services Shaid Sadoughi university

###### Street address

Bahonar square

###### City

Yazd

###### Postal code

##### Approval date

2009-06-14, 1388/03/24

##### Ethics committee reference number

24430

### Health conditions studied

#### 1

##### Description of health condition studied

Effect of tramadol on post tonsillectomy pain

##### ICD-10 code

Y45.0

##### ICD-10 code description

Opioids and related analgesics

#### 2

##### Description of health condition studied

Effect of ketamine on the post tonsillectomy pain

##### ICD-10 code

Y48.2

##### ICD-10 code description

Other and unspecified general anaesthetics

### Primary outcomes

#### 1

##### Description

Post-tonsillectomy pain

##### Timepoint

Each 10 min in the recovery room until 1 hour. Then each 2 hour until 12 hour in the ward.

##### Method of measurement

;CHEOPS score;

### Secondary outcomes

#### 1

##### Description

Sedation

##### Timepoint

2- 4- 6- 8- 12 hours post interance to ward

##### Method of measurement

RAMSY score

#### 2

##### Description

Systolic, diastolic, mean blood pressure

##### Timepoint

Each 5 min during surgery, 5- 10 - 15- 30- 60 min in the recovery

##### Method of measurement

Non invasive blood pressure

#### 3

##### Description

Negative Behaviors and hallucination

##### Timepoint

In the recovery room

##### Method of measurement

Visual

#### 4

##### Description

Heart rate  
**Timepoint**  
Each 5 min during surgery, 5- 10 - 15- 30- 60 min in the recovery  
**Method of measurement**  
EKG

## 5

**Description**  
Nausea, vomiting  
**Timepoint**  
IN the recovery room until 1 hour and in ward until 12 hours  
**Method of measurement**  
Visual and Asking the patient and her or his parents

## 6

**Description**  
Thr first time if needed analgesic  
**Timepoint**  
In the recovery and ward  
**Method of measurement**  
VAS

## 7

**Description**  
Starting time of fluids  
**Timepoint**  
In the ward  
**Method of measurement**  
Visual and Asking the patient and her or his parents

## **Intervention groups**

### 1

**Description**  
Ketamine infiltration in volume 2 cc - 0.5mg / kg, 1 cc into the area the submucousal of anterior fossa and beds of each tonsils after intubation, and three minutes before surgery starting.  
**Category**  
Prevention

### 2

**Description**  
Tramadol infiltration in volume 2 cc - 2mg / kg, 1 cc into the area the submucousal of anterior fossa and beds of each tonsils after intubation, and three minutes before surgery starting.  
**Category**  
Prevention

### 3

**Description**  
Normal saline infiltration in volume 2 cc - 1 cc into the area the submucousal of anterior fossa and beds of each tonsils after intubation, and three minutes before surgery

starting.  
**Category**  
Prevention

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Shahid Sadoughi Hospital  
**Full name of responsible person**  
Dr Vida Ayatollahi, Anesthesiologist, Assistant professor  
**Street address**  
Ebnesina str. Shahid ghandi ave. Shahid Sadoughi Hospital  
**City**  
Yazd

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Vice chancellor for research, .... University of shahid sadoughi medical university  
**Full name of responsible person**  
Dr Hassan Mozaffari  
**Street address**  
Yazd University of Medical Sciences, Bahonar Square  
**City**  
Yazd  
**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, .... University of shahid sadoughi medical university  
**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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Dr Vida Ayatollahi  
**Position**

Anesthesiologist, Member of anesthesia group,  
Assistant professor

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**Position**

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**Other areas of specialty/work**

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**City**

Yazd

**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*