

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Study of adding Ketamin to pre-incisional Bupivacain injection on post-operative pain relief after tonsillectomy, a Randomized, double blind clinical trial

#### Protocol summary

##### Summary

The aim of the study is to investigate the effect of adding ketamine to bupivacaine injection in incision site on the pain following tonsillectomy. In this prospective randomized double blind clinical trial, 63 patients, aged 40-30 years and ASA class I-II, scheduled for elective surgery were enrolled in 3 groups of 21 persons to receive ketamine (0.5mg/kg), bupivacaine 0.5% (2mg/kg), or ketamine (0.5mg/kg) and bupivacaine 0.5% (2mg/kg) in a total volume of 5 cc. After general anesthesia which is performed with the same method in all groups and at the end surgery, medication is injected in the tensile bed by the surgeon who is blind regarding the intervention type. Hemodynamic criteria, including heart rate and blood pressure, and incidence of postoperative pain with VAS (visual analogue scale) are measured at the end of surgery immediately after anesthesia, and 1, 6, and 24 hours after the surgery. Need to analgesics in 24 hours is also recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903181617N3**

Registration date: **2010-10-02, 1389/07/10**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2010-10-02, 1389/07/10

##### Registrant information

###### Name

Mansour Choubsaz

###### Name of organization / entity

Imam Reza Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1724 6708

###### Email address

mchoubsaz@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Kermanshah University of Medical Sciences and health Services

##### Expected recruitment start date

2012-04-20, 1391/02/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of adding Ketamin to pre-incisional Bupivacain injection on post-operative pain relief after tonsillectomy, a Randomized, double blind clinical trial

##### Public title

Study of adding Ketamin to pre-incisional Bupivacain injection on post-operative pain relief after tonsillectomy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: age 30-40 years old, ASA class I-II, patients whom scheduled for elective adenotonsillectomy surgery with general anesthesia. Exclusion criteria: History of hemodynamic disturbances, hypersensitivity to

study drugs, having impaired anatomical at the site of surgery

#### Age

From **4 years** old to **30 years** old

#### Gender

Both

#### Phase

4

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **63**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Kermanshah University of Medical Sciences

##### Street address

Pro-Vice-Chancellor for Research, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Postal code

#### Approval date

2010-09-19, 1389/06/28

#### Ethics committee reference number

7/420/6313

## Health conditions studied

### 1

#### Description of health condition studied

Sore throat

#### ICD-10 code

J06.0

#### ICD-10 code description

Acute laryngopharyngitis

## Primary outcomes

### 1

#### Description

heart rate

#### Timepoint

0-1-6-24 hours

#### Method of measurement

cardiac monitoring

### 2

#### Description

Blood pressure

#### Timepoint

0, 1, 6, 24 hours after surgery

#### Method of measurement

sphygmomanometer

## Secondary outcomes

### 1

#### Description

Sore throat

#### Timepoint

0, 1, 6, 24 hours after surgery

#### Method of measurement

visual analogue scale

## Intervention groups

### 1

#### Description

Ketamin 0.5 mg/kg, up to 5 ml, injection in tonsillar bed

#### Category

Treatment - Drugs

### 2

#### Description

Bupivacaine 0.5% 2mg/kg, up to 5 ml, injection in tonsillar bed

#### Category

Treatment - Drugs

### 3

#### Description

Ketamin 0.5mg/kg + Bupivacaine 0.5% 2mg/kg, up to 5 ml, injection in tonsillar bed

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kermanshah University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Farid Najafi

**Street address**Pro-Vice-chancellor for research, Kermanshah  
University of Medical Sciences**City**

Kermanshah

**Postal code**

6718938179

**Phone**

+98 83 1724 6708

**Fax**

+98 83 1724 4969

**Email**

mchoobsaz@kums.ac.ir

**Web page address**

mchoobsaz@kums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Kermanshah University of Medical Sciences and  
health Services**Full name of responsible person**

Dr. Samad Nourizad

**Street address**Kermanshah University of Medical Sciences and  
health Services**City**

Kermanshah

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**Kermanshah University of Medical Sciences and health  
Services**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**

Imam Reza Hospital

**Full name of responsible person**

Sara Joreir Ahmadi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work****Street address**Departement of Anesthesia and intensive care, Imam  
Reza Hospital**City**

Kermanshah

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Imam Reza Hospital

**Full name of responsible person**

Mansour Choubsaz

**Position**

Anesthesiologist/Assisstant Professor

**Other areas of specialty/work****Street address**Kermanshah University of Medical Sciences and  
Health Services**City**

Kermanshah

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**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*