Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 adenotonsilectomy 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

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
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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