Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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 recoverey 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 infilttration 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

Other areas of specialty/work

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Anesthesiologist, Assistant professor

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