

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison the effect of propofol and ketamine on the incidence of emergence cough in children undergoing Tonsillectomy.

Protocol summary

Summary

Coughing is one of the major complications during emergence from general anesthesia. Severe coughing during emergence from anesthesia may cause laryngospasm and bronchospasm in patients. In this study, patients will be randomly assigned to one of two groups: propofol and ketamine. At the end of surgery, by stopping anesthetic drugs, we will allow spontaneous respiration of patients will return. After that, patients in the 1st group will be received intravenous propofol 0.5mg/kg and in the 2st group, patients will be received intravenous ketamine 0.5mg.kg/Kg. After extubation, the number of cough, the amount of pain and agitation, as well as nausea and vomiting the patients will be evaluated by a nurse of anesthesia who is unaware of the patient's drug, until they leave the recovery room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101411662N11**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of propofol and ketamine on the incidence of emergence cough in children undergoing Tonsillectomy.

Public title

Comparison the effect of propofol and ketamine on the incidence of emergence cough

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: All patients whom will be candidate for Tonsillectomy, Age 3 to 12 years. The exclusion criteria: Patients are not in ASA class I and II; The patients has abnormalities in face or upper airway such as (maxillofacial fractures, tumors); Patients with respiratory problems like asthma; Allergic patients, those who have behavioral problems that needs to use sedative drugs before entering the operating room; patients who have cough due to any cause before surgery and the patients refuse to enter the study.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Shiraz Medical School Research Ethic Committee

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School,
Zand Blvd.

City

Shiraz

Postal code

197871345

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.sums.med.rec.1396.52

Health conditions studied**1****Description of health condition studied**

Cough following tonsillectomy

ICD-10 code

R05

ICD-10 code description

Pain in throat

Primary outcomes**1****Description**

Postoperative cough

Timepoint

30 minutes -2- 4 -8 -12 -24 hours post operation

Method of measurement

Questioners: Number of postoperative cough will be registered

Secondary outcomes**1****Description**

Postoperative pain and agitation

Timepoint

30 minutes,2, 4 ,8 ,12 and 24 hours post operation.

Method of measurement

Questioners: CHEOPS and Richmond

2**Description**

Nausea and Vomiting

Timepoint

30 minutes,2, 4 ,8 ,12 and 24 hours post operation.

Method of measurement

Questioners

Intervention groups**1****Description**

After spontaneous respiratory will be returned, patients in the 1st group received intravenous propofol.

Category

Treatment - Drugs

2**Description**

In the second group after spontaneous respiration will be returned, patients will be received intravenous ketamin.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dastghaib Training and Medical Center

Full name of responsible person

MohammaAli Sahmeddini

Street address

Hafez Avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology

Full name of responsible person

Seyed Basir Hashemi

Street address

Shiraz University Of Medical Sciences building, Zand Blvd.

City

Shiraz

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology

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**

Shiraz University Of Medical Sciences

Full name of responsible person

MohammadAli Sahmeddini

Position

Associate Professor of Anesthesiology

Other areas of specialty/work**Street address**

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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

