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

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Name of organization / entity

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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
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Position
Associate Professor of Anesthesiology
Other areas of specialty/work
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Person responsible for updating data

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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*