Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Effect of Oral Ketamine and Its Peritonsillar Injection in Pain Relief and the Related Phenomenon after a Tonsillectomy Operation

Protocol summary

Summary

The pain following tonsillectomy in children is common and due to its problems addressing and removing the pain would be essential. The effect of ketamine has been proved in this field. The objective of this study is to find out the best possible method of applying ketamine with maximum effect and minimum side effects after tonsillectomy. In this double blind, randomized clinical trial, 92 children with the range of 3-9 ages have been studied. At the entry standards for the study included: 1. selective tonsillectomy, 2. children with 3-9 ages, 3. ASAI, II. Meanwhile they did not have contraindication for ketamine and no internal disease. They divided randomly into 2 groups of oral and injection peritonsilar. All the patients were given 2 mg/kg of apple – juice, 30 minutes before surgery. Through which the injection group received apple-juice without ketamine and oral group received the same plus 5 mg/kg Ketamine. In peritonsilar group, 0/5 mg/kg Ketamine was injected around Tonsil and in oral group the same volume was injected around Tonsil 3 minutes before surgery. In this study, pain caused by surgery was studied 6 hours after tonsillectomy by modified scoring CHEOPS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811192080N2**
Registration date: **2010-03-18, 1388/12/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-03-18, 1388/12/27

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Reserch of Arak University of Medical Siences

Expected recruitment start date

2009-09-29, 1388/07/07

Expected recruitment end date

2010-01-20, 1388/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Oral Ketamine and Its Peritonsillar Injection in Pain Relief and the Related Phenomenon after a Tonsillectomy Operation

Public title

Comparison the Effect of Oral Ketamine and Its Peritonsillar Injection in Pain Relief and the Related Phenomenon after a Tonsillectomy Operation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-age 3-9 years 2-ASAI,II 3-elective tonsillectomy. Exclusion Criteria: 1-internal disease 2-contraindication for Ketamin (upper respiratory tract

infection, increase ICP, open eye surgery, seizure)

Age
From **3 years** old to **9 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **92**

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
Arak University of Medical Sciences

Street address
Alamol Hoda St.

City
Arak

Postal code

Approval date
1388-07-06, 769/01/-621

Ethics committee reference number
88-60-3

Health conditions studied

1

Description of health condition studied
Tonsillectomy

ICD-10 code
J03.9

ICD-10 code description
Acute tonsillitis, unspecified

Primary outcomes

1

Description
Pain after tonsillectomy

Timepoint
6 hour after tonsillectomy

Method of measurement
modified CHEOPS Score

Secondary outcomes

1

Description
Post operative complication

Timepoint
post operation

Method of measurement
check list

Intervention groups

1

Description
Oral ketamine with apple juice and peritonsillar injection of normal saline

Category
Treatment - Drugs

2

Description
Oral apple juice and peritonsillar injection of ketamine

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital

Full name of responsible person
Dr. Afsaneh Norouzi

Street address

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Siences

Full name of responsible person
Dr. Said Changizi Ashtiyani

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Deputy of Reserch, Arak University of Medical Siences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Siences
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

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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