

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 peritonsillar. 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 peritonsillar 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

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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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 Sciences

Full name of responsible person

Dr. Said Changizi Ashtiyani

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Deputy of Reserch, Arak University of Medical Sciences

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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 Sciences

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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Full name of responsible person

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Web page address**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