

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of addition of ketamine and dexamethasone to ropivacaine in peritonsillar infiltration to reduce postoperative pain

Protocol summary

Study aim

Comparison of pain and agitation and nausea and vomiting and time and dose of analgesic in ropivacaine plus dexamethasone and ropivacaine plus ketamine

Design

In this double-blind clinical trial study, 5 patients, aged 2 to 4 years, referred to Amir Kabir Hospital, Arak, were diagnosed with tonsillectomy and met inclusion criteria after obtaining informed consent. Patients under study were divided into two groups: dexamethasone and ketamine.

Settings and conduct

Given the double-blindness, only the primary investigator is aware of the groups and drugs used in this study, and patients and interns are responsible for collecting data from the groups and drugs used. This study was performed in Amirkabir hospital in Arak in 1398 in which all patients underwent tracheal anesthesia after entering the operating room. Then, the interventions are performed by the surgeon and their consequences are statistically analyzed. The extent of pain is determined by VAS ruler at 15, 30 and 2, 4, 8, 16, 24 hours, Agitation was measured by the Riker Sedation-Agitation scale at 15, 30, and 2, 4, 8, 16, and 24 minutes after surgery.

Participants/Inclusion and exclusion criteria

Children between the ages of 3 and 5 years are candidates for elective tonsillectomy in the absence of underlying disease and no history of motion sickness. If surgery lasts more than 2 hours and bleeding exceeds 10 cc / kg, the study will be excluded.

Intervention groups

In the first group, the surgeon delivered 2 cc of 0.5% ropivacaine solution plus dexamethasone 0.5 mg / kg (maximum 1 mg) with distilled water to CC 10 and in the second group 2 cc of ropivacaine solution 0.5% plus ketamine 0.5 mg / kg. With the help of distilled water, it reaches CC 10 and is injected into the peritonsillar fossa by the surgeon so that the injection is only in the sub mucus area. 5cm injection is given on each side.

Main outcome variables

Pain; Agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191022045200N1**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Fatemeh Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3774 4933

Email address

s_zeiho@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-08-22, 1398/05/31

Trial completion date

2019-09-22, 1398/06/31

Scientific title

Comparison of addition of ketamine and dexamethasone to ropivacaine in peritonsillar infiltration to reduce postoperative pain

Public title

The effect of dexamethasone and ketamine on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 1 to 4 years old candidate for elective tonsillectomy Absence of underlying cardiovascular, respiratory, kidney, liver and brain diseases No history of motion sickness

Exclusion criteria:

Surgery lasts more than 4 hours Bleeding action greater than 10 cc / kg

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **92**

Actual sample size reached: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, 5 patients, aged 4-5 years, referred to Amir Kabir Hospital in Arak, were diagnosed with tonsillectomy and met inclusion criteria after obtaining informed consent. Patients were then randomly divided into two groups of dexamethasone plus bupivacaine and ketamine plus bupivacaine.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness Due to the double blindness of the study, only the relevant expert in this study is aware of the type of study and study groups, while patients are not aware of the type of drug being used. Also, the intern who is responsible for the design of the checklist is not aware of the groups based on the injectable drug and only identifies the groups based on A and B and fills the checklists accordingly.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.ARAKMU.REC.1397.062

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

Tonsillectomy

ICD-10 code

J35.03

ICD-10 code description

Chronic tonsillitis and adenoiditis

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

Pain score on the Visual Analogue Scale

Timepoint

Minutes 15, 30 and 2, 4, 8, 16, 24 hours after surgery

Method of measurement

Visual Analogue Scale ruler

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

Patient Agitation rate

Timepoint

Minutes 15, 30 and 2, 4, 8, 16, 24 hours after surgery

Method of measurement

Riker Sedation-Agitation scale

Intervention groups

1

Description

First Intervention group: 2 cc of ropivacaine 0.5% plus dexamethasone 0.5 mg / kg (maximum 1 mg) with distilled water delivered to CC 10 and injected into the peritonsillar fossa by the surgeon so that the injection was only in the sub mucus area. 5cm injection is given on each side.

Category

Treatment - Drugs

2

Description

Second Intervention group: CC 2 of 0.5% ropivacaine solution plus 0.5 mg / kg ketamine with distilled water is delivered to CC 10 and injected into the peritonsillar fossa by the surgeon so that the injection is only in the sub mucus area. 5cm injection is given on each side.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امیرکبیر اراک

Full name of responsible person

فاطمه حسینی

Street address

Amirkabir Hospital, Parastar Sq., Shiroudi St.

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3848176341

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

علیرضا کمالی

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Payambar-e-azam Complex, Arak University of
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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Hoseini

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

student

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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