

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Study of the effect of Dexmedetomidine Premedication on Pediatric Tonsillectomy Anesthesia

Protocol summary

Study aim

Study of the effect of Dexmedetomidine Premedication on Pediatric Tonsillectomy Anesthesia

Design

This study is one-blinded clinical trial. The study population will be included all children aged 4-10 years who are candidates for Tonsillectomy referring to the ENT ward of Imam Khomeini hospital of Kermanshah city. 44 eligible patients will be selected conveniently and randomly will be assigned to intervention and control groups.

Settings and conduct

This study which will be conducted in Imam Khomeini hospital of Kermanshah city is one-blinded one that the participants will not know what medicine they will receive. At the beginning of the study, the severity of the sensory symptoms, including paresthesia and pain, is recorded in a checklist in both groups. The bleeding, nausea, vomiting, agitation will be investigated after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 4-10 years old children undergoing tonsillectomy. Exclusion criteria: Sensitization to opioids or local anesthetics; Patients suffering from asthma, kidney disease, liver, acute pharyngitis and coagulation disorders

Intervention groups

The intervention group will receive 200 micrograms of Dexmedetomidine as infusion at a rate of 0.5 µg/kg/h in addition to intravenous thiopental 5 mg/kg with atracurium 0.5 mg/kg. The control group only to intravenous thiopental with 0.5 mg/kg atracurium will receive 5 mg/kg.

Main outcome variables

Bleeding, nausea and vomiting, agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N108**
Registration date: **2018-12-15, 1397/09/24**
Registration timing: **prospective**

Last update: **2018-12-15, 1397/09/24**

Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-31, 1397/10/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Dexmedetomidine Premedication on Pediatric Tonsillectomy Anesthesia

Public title

Study of the effect of Dexmedetomidine Premedication on Pediatric Tonsillectomy Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

4-10 years old children undergoing tonsillectomy

Exclusion criteria:

Sensitization to opioids or local anesthetics Patients suffering from asthma, kidney disease, liver, acute pharyngitis and coagulation disorders

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study patients were blinded to the study groups, dosage of the drug and the manufacturer of the drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

ir.kums.rec.1397.421

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

Tonsillectomy

ICD-10 code

28.92

ICD-10 code description

tonsillectomy

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

Nausea and Vomiting

Timepoint

After surgery

Method of measurement

Ask the patient and doctor's observation

2**Description**

Agitation

Timepoint

After surgery

Method of measurement

doctor's observation

3**Description**

Bleeding

Timepoint

After surgery

Method of measurement

doctor's observation

Secondary outcomes

empty

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

The intervention group will receive 200micrograms of Dexmedetomidine as infusion at a rate of 0.5 µg/kg/ h in addition to intravenous thiopental 5 mg / kg with atracurium 0.5 mg / kg.

Category

Treatment - Drugs

2

Description

The control group only to intravenous thiopental with 0.5 mg / kg atracurium will receive 5 mg / kg .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Gholamreza Rodaber

Street address

Street, Emam Khomeini Hospital

City

Kermanshah

Province

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6718743161

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Email

Saeidrood@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

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fnajafi@kums.ac.ir

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Gholamreza Roodaber

Position

Resident of Anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Bahman Roshani

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Gholamreza Roodaber

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments