

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Submucosal injection of dexmedetomidine in reduction of postoperative pain in pediatric tonsillectomy

Protocol summary

Study aim

Comparison of demographic characteristics in the control group with the intervention group; determining the intensity of pain after tonsil surgery in the intervention group at 4, 8, 12, and 24 hours; comparison of pain intensity after tonsil surgery in the intervention and control groups at 4, 8, 12, and 24 hours; comparison of heart rate during tonsillectomy in intervention and control groups; Comparison of systolic and diastolic blood pressure during tonsillectomy in intervention and control groups; comparison of arterial blood oxygen saturation percentage during tonsillectomy in the intervention and control groups; comparison of the duration of anesthesia during tonsillectomy in intervention and control groups; comparison of the recovery period in intervention and control group

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 35 patients. The rand function of Excel software was used for randomization.

Settings and conduct

A double-blind randomized prospective clinical trial in the center Heshmatieh Sabzevar educational therapy. The drug dexmedetomidine and normal saline with the same volume and in the same shape syringes are prepared by an anesthetist who knows the content of the research and is fully justified and is marked with code A or B. In this way, the researcher evaluates the patients only based on the code without knowing whether the patient is in the dexmedetomidine group or normal saline.

Participants/Inclusion and exclusion criteria

Candidate for tonsillectomy surgery; 4 to 15 years

Intervention groups

Intervention group with dexmedetomidine and normal saline

Main outcome variables

"Intensity of pain after tonsil surgery"; "Arterial blood oxygen saturation percentage during tonsillectomy";

"Heartbeat during tonsillectomy"; "Systolic and diastolic blood pressure during tonsillectomy"; "Recovery time"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220508054785N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

Mahdieh Kalateh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 5758

Email address

kalatehm95@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Submucosal injection of dexmedetomidine in reduction of postoperative pain in pediatric tonsillectomy

Public title

Injection of dexmedetomidine in reduction of pain in pediatrics tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for tonsillectomy surgery 4 to 15 years ASA class I&II No peritonsillar abscess No chronic pain Not taking painkillers 24 hours before surgery

Exclusion criteria:

Parents' lack of consent to continue attending the study
History of allergy to any medicine
Coagulation disorder
Liver disorders
Uncontrolled diabetes (ASA 3 and above)
Active upper respiratory tract infection
Occurrence of complications during surgery
Increasing the recovery period to more than 60 minutes
Increasing the duration of surgery

Age

From **4 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

this project which is actually a clinical trial aims to investigate the injection of dexmedetomidine in reduction of pain in pediatrics tonsillectomy patients who are divided into intervention and control group based on permutation block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug dexmedetomidine and normal saline with the same volume and in the same shape syringes are prepared by an anesthetist who knows the content of the research and is fully justified and is marked with code A or B. In this way, the researcher evaluates the patients only based on the code without knowing whether the patient is in the dexmedetomidine or normal saline group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Medical School, Education Vice-Chancellor, University Campus Building, Tawheed Shahr Blvd., Sabzevar Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2022-02-13, 1400/11/24

Ethics committee reference number

IR.MEDSAB.REC.1400.153

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

Tonsillectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Severity of pain after tonsil surgery

Timepoint

4, 8, 12 and 24 after the intervention

Method of measurement

Faces Pain Scale-Revised (FPS-R)

Secondary outcomes

empty

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

Intervention group: anaesthesia is induced by fentanyl 4 µg/kg & propofol 2 µg/kg & atracurium 0.4 µg/kg after 3 minutes tracheal intubation and ventilation are performed and anaesthesia is maintained with nitrous oxide 50% and oxygen 50% and isoflurane 1.2 . the children were locally infiltrated with 1 µg/kg

dexmedetomidine into the pretonsillar space by surgeon
{ between upper and lower parts of tonsils}
Category
Treatment - Drugs

2

Description

Control group: anaesthesia is induced by fentanyl 4 µg/kg & propofol 2 µg/kg & atracurium 0.4 µg/kg after 3 minutes tracheal intubation and ventilation are performed and anaesthesia is maintained with nitrous oxide 50% and oxygen 50% and isoflurane 1.2 .after anaesthesia normal saline with the same volume and in the same shape syringes with dexmedetomidine are prepared and were locally infiltrated into the peritonsillar space by surgeon.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmatieh Sabzevar Medical Education Center
Full name of responsible person
Mahdieh kalateh
Street address
Medical School, Education Vice-Chancellor, University
Campus Building, Tawheed Shahr Blvd., Sabzevar
Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
mahdieh.kalateh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Hossein Saghi
Street address
Medical School, Education Vice-Chancellor, University
Campus Building, Tawheed Shahr Blvd., Sabzevar
Town
City
Sabzevar
Province
Razavi Khorasan
Postal code

9617913112
Phone
+98 51 4401 8300
Email
saghi9@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Shakiba mozari
Position
Assistant professor, specialist physician, academic
staf
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Medical School, Education Vice-Chancellor, University
Campus Building, Tawheed Shahr Blvd., Sabzevar
Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8300
Email
sh.mozari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Shakiba mozari
Position

Assistant professor, specialist doctor, academic staff

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Medical School, Education Vice-Chancellor, University
Campus Building, Tawheed Shahr Blvd., Sabzevar
Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 8300

Email

sh.mozari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mahdieh Kalateh

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Medical School, Education Vice-Chancellor, University
Campus Building, Tawheed Shahr Blvd., Sabzevar
Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 8300

Email

mahdieh.kalateh@yahoo.com

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

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

--

When the data will become available and for how long

--

To whom data/document is available

--

Under which criteria data/document could be used

--

From where data/document is obtainable

--

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

--

Comments