Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 &and propefol 2 µg/kg & atracurium 0.4 µg/kg after 3 minutes tracheal intubation and ventilation are performed and anaesthesia is maintained with nitrousoxide50% and oxygen 50% and isoflorane1.2 . the children were locally infiltrated with 1 µg/kg

dexmedetomidine into the pretonsillar space by sergeon { between upper and lower parts of tonsils}

Category

Treatment - Drugs

2

Description

Control group: anaesthesia is induced by fentanyl 4 µg/kg &and propefol 2 µg/kg & atracurium 0.4 µg/kg after 3 minutes tracheal intubation and ventilation are performed and anaesthesia is maintained with nitrousoxide50% and oxygen 50% and isoflorane1.2 .after anaesthesia normal saline with the same volume and in the same shape syringes with dexmetedomine 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

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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
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When the data will become available and for how long
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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
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Comments