

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation the effect of dexmedetomidine on emergence agitation in children undergoing anesthesia with sevoflurane

Protocol summary

Study aim

The purpose of this study will be to assess evaluation the effect of dexmedetomidine on emergence agitation in children undergoing anesthesia with sevoflurane

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2

Settings and conduct

In Urmia Imam Khomeini hospital operating room Group D (Study group) will be received intravenous dexmedetomidine 0.5 microgram per kilogram in 10 minutes and Group C (control group) will be received intravenous saline 0.9% after induction of general anesthesia. After arrival to postanesthesia care unit (PACU), incidence of emergence agitation and pain will be assessed through six time points(after extubation, leaving the OR, on admission to PACU, 10, 20, and 30 min after arrival in PACU by four-point agitation scale and visual analog scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: those between 2 and 8 years of age; classified as ASA status I; scheduled for either an adenoidectomy alone or both an adenoidectomy and tonsillectomy; general anesthesia Exclusion criteria included: mental retardation or developmental delay; neurologic disease; a history of asthma or the other lung diseases; chronic cough; upper respiratory tract infection within 4 weeks of surgery; patients with abnormal airway.

Intervention groups

Intervention group: will be received intravenous dexmedetomidine 0.5 microgram per kilogram in 10 minutes after induction of anesthesia Control group: will be received intravenous saline 0.9% after induction of genera

Main outcome variables

agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N14**

Registration date: **2019-05-07, 1398/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-07, 1398/02/17**

Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of dexmedetomidine on emergence agitation in children undergoing anesthesia with sevoflurane

Public title

The effect of dexmedetomidine on emergence agitation after anesthesia with sevoflurane

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

2 to 8 years old American society of Anesthesiology physical status I adenoidectomy alone or both an adenoidectomy and tonsillectomy general anesthesia with sevoflurane

Exclusion criteria:

mental retardation or developmental delay neurologic disease history of asthma or the other lung diseases chronic cough, upper respiratory tract infection within 4 weeks of surgery patients with abnormal airway

Age

From **2 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Seventy patients who recruited as eligible population and assigned to one of two groups(35 patients in each group) by using Random Allocation Software 2.0. Group D (Study group) will be received intravenous dexmedetomidine 0.5 microgram per kilogram and Group C (control group) will be received intravenous saline 0.9%

Blinding (investigator's opinion)

Double blinded

Blinding description

Dose calculation, drug preparation, and administration will be done by attending anesthesiologist who is not involved or have not participated in this trial.after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-01-16, 1397/10/26

Ethics committee reference number

IR.UMSU.REC.1397.411

Health conditions studied

1

Description of health condition studied

بی قراری

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

agitation

Timepoint

After extubation, leaving the OR, on admission to PACU, 10, 20, and 30 min after arrival in PACU

Method of measurement

four-point scale

Secondary outcomes

1

Description

pain

Timepoint

After extubation, leaving the OR, on admission to recovery, 10, 20, and 30 min after arrival in recovery

Method of measurement

face leg activity cry consolability

2

Description

Mean arterial pressure

Timepoint

Minutes 5, 10, 15 and 20 during surgery

Method of measurement

None invasive barometer pressure

3

Description

Heart rate

Timepoint

Minutes 5, 10, 15 and 20 during surgery

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group: will be received intravenous dexmedetomidine 0.5 microgram per kilogram in 10 minutes after induction of anesthesia

Category

Prevention

2

Description

Control group: will be received intravenous saline 0.9% after induction of general anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital, operating room B

Full name of responsible person

Shahryar Sane

Street address

Ershad Avenue, Modarres Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

Email

emam-h-urm@umsu.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

research@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Avenue

City

Urmia

Province

West Azarbaijan

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5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Person responsible for scientific inquiries

Contact

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Email

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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