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)

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+98 44 3223 4897

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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 sevoflorane

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 commitee 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

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Ershad Avenue, Modarres Avenue

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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

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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

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Person responsible for updating data

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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