Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Clinical trial Comparison of intravenous dexmedetomidine and intravenous Apotel and combined of those (intravenous Apodex) on postoperative emergence agitation & pain after Adenotonsilectomy with Sevofloran in children

Protocol summary

Summary

(1) Objectives: Evaluation of the effects of intravenous dexmedetomidine and intravenous Apotel and combined of those (intravenous Apodex) on postoperative emergence agitation & pain after adenotonsilectomy in children (2) Design: randomized, double blind controlled with placebo. (3) Setting and conduct: After set up monitoring & fixation of venous catheter & infusion of serum crystalloid, all patients will be received 0.5 mg/kg dexamethazone, 1 µg/kg fentanyl, 0.02 mg/kg atropine as premedication. subsequently induction of anesthesia will be applied with 2 mg/kg propofol & 1 mg/kg succynylcolin, then patients will be intubated. maintenance of anesthesia until to the end of surgery will be continued with combination of 50% oxygen, 50% nitrous oxide, and 2-3% of sevoflurane concentration. (4) Participants including major eligibility criteria. Inclusion criteria: take Informed consent from parents to enter the study; patients between 2-12 old age candidate for :Adenotonsilectomy; Physical status 1 and 2 classification of "American Society of Anesthesiologists" (ASA). Exclusion criteria: History of any cardiac, kidney, hepatic, or neurologic (convulsion) disease; Respiratory disease (Asthma or respiratory allergy); History of allergic reaction to the study drugs; History of upper airway infection in the last 4 weeks; use of any type of sedative drugs at the night before surgery; evidence of severe obstractive sleep apnea (OSA) Sample size: 132 person. (5) Intervention: Patients will be received 15 mg/kg Apotel in 50 ml normal saline in group A, 1 mcg/kg dexmedetomidine in 50 ml normal saline in group D, 10 mg/kg Apotel and 0.3 mcg/kg dexmedetomidine in 50 ml normal saline in group AD, and merely 50 ml normal saline in group S or control group just 15 minutes before termination of surgery during 10 minutes. (6) Main outcome measures: when patient is transferred to postanesthesia care unit (PACU), emergence agitation (EA) using five score (Col et al) criteria, and pain using 10 score TPPPS criteria will be measured and recorded in advent to the recovery room (T0) and in 5,15,30 minutes thereafter and when the patient discharge from PACU. As well as 6 and 24 hours after discharge from PACU the proportion of EA & pain will be measured and recorded in the ward using aforementioned criteria. patient discharge from PACU will be based on Aldrete 10 score criteria. patient with Aldrete score > 9, and when do not have nausea and vomiting, and with controlled EA & pain will be discharged from PACU, and the time of stay in PACU will be recorded.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016092930049N1**
Registration date: **2017-04-12, 1396/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

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Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research of Kurdistan University of Medical Sciences

Expected recruitment start date
2017-04-04, 1396/01/15
Expected recruitment end date
2018-04-04, 1397/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial Comparison of intravenous dexmedetomidine and intravenous Apotel and combined of those (intravenous Apodex) on postoperative emergence agitation & pain after Adenotonsilectomy with Sevofloran in children

Public title
Effects of intravenous dexmedetomidine and intravenous Apotel and combined of those (intravenous Apodex) on postoperative emergence agitation & pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: take Informed consent from parents to enter the study; patients between 2-12 old age candidate for Adenotonsilectomy; Physical status 1 and 2 classification of "American Society of Anesthesiologists" (ASA). Exclusion criteria: History of any cardiac, kidney, hepatic, or neurologic (convulsion) disease; Respiratory disease (Asthma or respiratory allergy); History of allergic reaction to the study drugs; History of upper airway infection in the last 4 weeks; use of any type of sedative drugs at the night before surgery; evidence of severe obstractive sleep apenea (OSA)
Age
From **2 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
-

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Pasdaran street, Sanandaj
City
Sanandaj
Postal code
Approval date
2016-12-26, 1395/10/06
Ethics committee reference number
IR.MUK.REC.1395.275

Health conditions studied

1

Description of health condition studied
Adenotonsilectomy
ICD-10 code
J35.3
ICD-10 code description
Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description
Emergence agitation
Timepoint
in advent to the recovery room (T0) and in 5,15,30 minutes thereafter and when the patient discharge from PACU. As well as 6 and 24 hours after discharge from PACU
Method of measurement
five score criteria described by Col for evaluate emergence agitation

2

Description
pain
Timepoint
in advent to the recovery room (T0) and in 5,15,30 minutes thereafter and when the patient discharge from PACU. As well as 6 and 24 hours after discharge from PACU
Method of measurement
modified 10 score TPPPS criteria for evaluate of pain in children

Secondary outcomes

1

Description
Delirium
Timepoint
in advent to the recovery room (T0) and in 5,15,30 minutes thereafter and when the patient discharge from PACU. As well as 6 and 24 hours after discharge from PACU
Method of measurement
20 score PAED criteria for evaluate delirium in children

2

Description
Time to need the first rescue analgesic dose
Timepoint
Period of time from PACU admitance until the first need to analgesics
Method of measurement
By recording period of time between PACU admitance to the first need to analgesics

3

Description
Rate of need to analgesics
Timepoint
amount of analgesics usage for pain & EA relief
Method of measurement
By recording of amounts of analgesic usage in PACU & ward

4

Description
Nausea & vomiting
Timepoint
consideration for beeing Nausea & vomiting
Method of measurement
Have or not have

5

Description
Time of stay in PACU
Timepoint
Period of time from admitance to discharge from PACU
Method of measurement
recording period of time from admitance to discharge from PACU based on Aldrete criteria > 9

Intervention groups

1

Description
in group A 15 mg/kg of intravenous acetaminophen in 50 ml normal saline, will be infused 15 minutes before termination of surgery during 10 minutes.
Category
Treatment - Drugs

2

Description
in group D 1 mcg/kg of intravenous dexmedetomidine in 50 ml normal saline, will be infused 15 minutes before termination of surgery during 10 minutes.
Category
Treatment - Drugs

3

Description
in group AD 10 mg/kg of intravenous acetaminophen and 0.3 mcg/kg dexmdetomidine in 50 ml normal saline, will be infused 15 minutes before termination of surgery during 10 minutes.
Category
Treatment - Drugs

4

Description
in group S or control group merely 50 ml normal saline, will be infused 15 minutes before termination of surgery during 10 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital of Sanandaj
Full name of responsible person
Dr.Farzad Sarshivi
Street address
Kosar hospital, Kurdistan University of Medical Sciences, Pasdaran street, Sanandaj
City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Kurdistan University of Medical Sciences

Full name of responsible person
Dr.Ebrahim Ghaderi

Street address
Kurdistan University of Medical Sciences, Pasdaran street, Sanandaj

City
Sanandaj

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research of Kurdistan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Dr.Farzad Sarshivi

Position
Anesthesiologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty