

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effect of intranasal ketamin and intranasal dexmedetomedin versus placebo on sedation,bleeding,pain & agitation in children undergoing adenotonsilectomy

Protocol summary

Study aim

Effects of intranasal ketamine and dexmedetomidine versus placebo on preoperative pediatric rest, intraoperative bleeding, restlessness and pain in patients undergoing adenotonsillectomy

Design

A randomized, triple-blind, placebo-controlled clinical trial

Settings and conduct

In this study, children in need of elective adenotonsillectomy surgery were recruited at Besat Hospital in Hamedan in 1979. Patients were randomly divided into three groups of dexmedetomidine (D), ketamine (k) and placebo control (normal saline). (NS) are segmented. Patients were given 2 mg / kg dexmedetomidine or 5 mg / kg ketamine 30 minutes prior to induction of anesthesia and in the control group received 5 drops of 9% normal saline with 2 mg syringe when the child was present with their parents. Be. Medications are poured into both nostrils. Blood pressure, pulse rate, and Spo2 are measured every 15 minutes after the drug is administered until the patient leaves the recovery room.

Participants/Inclusion and exclusion criteria

Children 4 to 12 years old undergoing adenotonsillectomy surgery • Inclusion criteria 1. Age 4 to 12 years 2. Candidate for tonsillectomy 3. Patient class according to American Society of Anesthesiology (ASA) ratings one and two • Exclusion criteria 1. Drug sensitivity to ketamine or dexmedetomidine 2. Mental retardation 3. Hyperactivity 4. Psychiatric drug use 5. History of heart, kidney, liver disease 6. Any pathological problems in the nose 7. Patients returning to the operating room due to postoperative bleeding

Intervention groups

- Intervention group 1: Intranasal ketamine 5 mg / kg •
- Intervention group 2: Intranasal dexmedetomidine 2 µg

/ kg • Comparison Group: Normal intranasal saline 2 cc

Main outcome variables

Assessment of relaxation before anesthesia, Relaxation was assessed 15 and 30 minutes before anesthesia using a standard questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100518003954N9**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **retrospective**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

Registrant information

Name

Mohammad Hossein Bakhshaei

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1826 9403

Email address

bakhshaei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01
Actual recruitment start date
 2018-08-23, 1397/06/01
Actual recruitment end date
 2019-08-23, 1398/06/01
Trial completion date
 2019-08-23, 1398/06/01

Scientific title
 Comparing the effect of intranasal ketamin and intranasal dexmedetomedin versus placebo on sedation,bleeding,pain & agitation in children undergoing adenotonsilectomy

Public title
 The effect of ketamine and dexmedetomidine on preoperative sedation and intraoperative bleeding and analgesia during recovery

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children undergoing adenotonsillectomy surgery who do not have concomitant disease.
Exclusion criteria:
 Drug sensitivity to ketamine or dexmedothymidine
 Mental retardation ADHD Psychiatric drug use History of heart, kidney, liver disease Any pathological problems in the nose Patients who return to the operating room due to postoperative bleeding

Age
 From **4 years** old to **12 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
 Target sample size: **3**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
 3 groups of A & B & c, each of which 31 patients were studied and a total of 93 patients were evaluated at the end
 Actual sample size reached: **93**

Randomization (investigator's opinion)
 Randomized

Randomization description
 For this purpose we will use the hexadecimal random blocks method. For this purpose, we produce six sheets of paper. On the two sheets the letter K means "Ketamin" and on the other two sheets the letter D "dexmedetomedin" and on the two sheets the letter P means Placebo. Mix the sheets together and place in a drawer. On referral to each eligible patient, one leaf was randomly drawn and assigned to one of three study

groups according to this leaflet, whether K, D or P. It should be noted that the drawn sheets will not be returned to the drawer until all six sheets have been drawn. After randomly pulling out all six sheets, all sheets will be returned to the drawer and the same operation will continue for the next six patients until the desired sample size (93 patients) is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the researcher first presents the necessary explanations to the child's father {patient's father}. In the drawer she receives from the nurse, the patient is left unaware of the chosen group. Questionnaires and surveys are carried out by the researcher to the end. The analyzer analyzes the data based solely on the three types of groups a, b, and c, and after receiving the information from the analyzer, the nurse determines the relationship between the groups at the end.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan university of Medical sciences

Street address

Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

6515713834

Approval date

2018-07-09, 1397/04/18

Ethics committee reference number

IR.UMSHA.REC.1397.418

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of ketamine or dexmedetomidine on placebo for preoperative relaxation& Intraoperative hemorrhage and postoperative analgesia in patients undergoing adenotonsillectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Relaxation before intranasal injection of ketamine or dexmedetomidine in adenotonsillectomy

Timepoint

Evaluation of sedation before adenotonsillectomy in children receiving intranasal ketamine or dexmedetomidine versus placebo 15 and 30 minutes after drug administration

Method of measurement

Questionnaire according to clinical criteria

Secondary outcomes

1

Description

Evaluation of the effect of medication on intraoperative bleeding

Timepoint

At the end of surgery.

Method of measurement

Calculation of bleeding inside the suction bottle and bleeding medical gases

2

Description

Evaluation of the effect of medication on postoperative pain and restlessness

Timepoint

Evaluation of patient pain and restlessness at 15, 30, 45 and 60 minutes after surgery in recovery

Method of measurement

Using the standard questionnaire: Children's Hospital of Eastern Ontario pain score and Pediatric Anesthesia Emergency Delirium (PAED) scal

Intervention groups

1

Description

Intervention group: This study is a randomized clinical trial of children in need of elective adenotonsillectomy with ASA status I and II in Hamadan Baysat Hospital in 1397. After sufficient explanation is given to parents if they consent to participate in the informed consent study. Patients were randomly divided into three groups: dexmedetomidine (D), ketamine (k) and placebo (normal saline (NS)). Patients were given 2µg / kg of dexmodetimidine or 5mg / kg of ketamine 30 minutes before induction of anesthesia and in the control group received 5 drops of 9% normal saline with 2mg syringe when the child was present with their parents. Medications are given in both nostrils in recumbent position. Blood pressure, pulse rate, and Spo2 were measured every 15 minutes until the patient was discharged from the recovery room. Patients were

treated with 1mg / kg fentanyl intravenously and anesthetized with isoflurane 20 minutes prior to anesthesia. Completion of the procedure for all patients for analgesia is 15 mg / kg of acetaminophen infused with 20 cc normal saline. Intervention group 1: Intranasal ketamine 5 mg / kg once 30 min before anesthesia • Intervention group 2: Intranasal dexmedothymidine 2 micrograms per kg 30 minutes before anesthesia • Comparison group: Normal saline intravenously Nose 4 drops once 30 minutes before anesthesia begins

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Mohammadhossein Bakhshaei

Street address

Bassat Hospital, Shahid Beheshti Boulevard

City

Hamedan

Province

Hamadan

Postal code

6515713834

Phone

+98 81 3264 0020

Email

bakhshaei@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Bassat Hospital, Shahid Beheshti Boulevard

City

hamedan

Province

Hamadan

Postal code

6516713834

Phone

+98 81 3264 0020

Email

bakhshaei@umsha.ac.ir

Grant name

Hamadan University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Mohsen Zarei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

Street address

Bassat Hospital, Beheshti Blvd.

City

Hamedan

Province

Hamadan

Postal code

6515713834

Phone

+98 81 3264 0020

Email

drm.zarei@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Hossein Bakhshaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Bassat Hospital, Shahid Beheshti Boulevard

City

hamedan

Province

Hamadan

Postal code

6515713834

Phone

+98 81 3264 0021

Email

bakhshaei@umsha.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Mohsen Zarei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Bassat Hospital, Shahid Beheshti Boulevard

City

Hamedan

Province

Hamadan

Postal code

6515713834

Phone

+98 81 3264 0021

Email

drm.zarei@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data of study participants, after unidentifiable individuals, can be shared in most tables and graphs.

When the data will become available and for how long

Start data access period 6 month after printing results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

It is possible to use the data after obtaining the written consent of the researchers

From where data/document is obtainable

Dr. Mohammad Hossein Bakhshai :

bakhshaei@umsha.ac.ir Dr. Mohsen Zarei :
drm.zarei@yahoo.com

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

If you send an email, the data request will be answered within a week.

Comments