

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

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##### 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 dexmedetomidine 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 Spo<sub>2</sub> 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 dexmedetomidine 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

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##### Phone

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##### Email

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## 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

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#### 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

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**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

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Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**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**