

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of oral premedication of midazolam, ketamine and dexmedetomidine in sedation and facilitation of separation of children from parents for induction of anesthesia

#### Protocol summary

##### Study aim

Oral premedication of midazolam, ketamine and dexmedetomidine in sedation and facilitation of separation of children from parents will be compared.

##### Design

Clinical trial with 3 parallel groups of intervention, double-blind, randomized by block method, phase 3 on 153 patients

##### Settings and conduct

In this double-blind randomized clinical trial study, eligible patients in Arak University of Medical Sciences affiliated hospitals, after obtaining informed consent, enter the study and are randomly divided into 3 groups by block method. The drug (midazolam or ketamine or dexmedetomidine) is given by the intern, who is unaware of the type of drug being prescribed, into syringe under the child's tongue to be swallowed with a short pause in the mouth. Sedation score, ease of separation and acceptance of anesthesia drug as well as blood pressure, heart rate, arterial oxygen saturation, time to get Aldrete score 8 and above as well as side effects (nausea and vomiting, hypotension, bradycardia) are recorded and studied.

##### Participants/Inclusion and exclusion criteria

Age 2 to 7 years Weight between 10 and 30 kg ASA I or II  
Candidate for elective surgery except for fractures  
Absence of any fracture operation No history of allergies  
Absence of liver, kidney and cardiopulmonary disorders  
Lack of long-term use of anticonvulsant drugs, sleep disorders  
Absence of speech or communication problems  
Absence of gastrointestinal disorders (due to oral administration of drugs)  
The duration of surgery is less than 120 minutes  
Consent of parents and guardians of the child

##### Intervention groups

Eligible children are randomly divided into 3 intervention groups that will receive orally before the surgery, the

first group: midazolam, the second group: ketamine and the third group: dexmedetomidine.

##### Main outcome variables

sedation score; Ease of separation score; Acceptance of drug Score - Each based on the relevant table

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211007052693N1**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **prospective**

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

##### Registration date

2021-11-20, 1400/08/29

##### Registrant information

##### Name

Aref Zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-11, 1400/09/20

##### Expected recruitment end date

2022-02-19, 1400/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of oral premedication of midazolam, ketamine and dexmedetomidine in sedation and facilitation of separation of children from parents for induction of anesthesia

**Public title**

Comparison of oral premedication of midazolam, ketamine and dexmedetomidine in sedation and facilitation of separation of children from parents for induction of anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 2 to 7 years Weight between 10 and 30 kg ASA I or II  
Candidate for elective surgery except for fractures  
Absence of any fracture operation No history of allergies  
Absence of liver, kidney and cardiopulmonary disorders  
Lack of long-term use of anticonvulsant drugs, sleep disorders  
Absence of speech or communication problems  
Absence of gastrointestinal disorders (due to oral administration of drugs)  
The duration of surgery is less than 120 minutes  
Consent of parents and guardians of the child

**Exclusion criteria:**

Any unpredictable complications around the operation that affect the variables being evaluated

**Age**

From **2 years** old to **10 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **153**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this double-blind randomized clinical trial study, 153 patients 2 to 10 years old, candidates for elective surgery, enter the study after obtaining the informed consent of the patient's parents or guardian. None of the children should receive sedatives before entering the operating room and they are randomly divided into 3 groups by block method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Unaware of the type of drug being prescribed, the intern pours the drug under the child's tongue by the syringe

containing the intervention drug to be swallowed with a short pause in the mouth. The exact method is that in each group, after calculating the amount of drug based on the child's weight, to standardize and create an acceptable taste, one milliliter of 20% dextrose solution is added to the calculated intervention drug for each patient. Finally, to match the groups, the volume of the prescribed material with distilled water is increased to 5 ml. This double-blind study will be performed in such a way that patients with informed consent to enter the plan will not be aware of the type of drug used. Also, the intern, who is responsible for completing the questionnaires and recording the data, is not aware of the patients in the study groups and will not be aware of the type of oral solution. And will only complete the questionnaires based on the numbers to be assigned to the operating room by the anesthesiologist in charge of the project.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Sardasht, Basij Square, University of Medical Sciences, University Complex of the Holy Prophet (PBUH), Deputy of Research and Technology

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Arak

**Province**

Markazi

**Postal code**

3848176341

**Approval date**

2021-09-05, 1400/06/14

**Ethics committee reference number**

IR.ARAKMU.REC.1400.155

**Health conditions studied****1****Description of health condition studied**

anesthesia

**ICD-10 code****ICD-10 code description**

## 2

### **Description of health condition studied**

sedation

### **ICD-10 code**

### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

sedation score

#### **Timepoint**

The observation sedation score is measured before the medication is prescribed (midazolam, ketamine, and dexmedetomidine) and then when the child is separated from the parents.

#### **Method of measurement**

Determine the sedation score by observing based on scoring from 1 to 5 based on the table from 1 to 5, respectively: agitated, alert, calm, drowsy and asleep

### 2

#### **Description**

Ease of separation score

#### **Timepoint**

When separating children from their parents

#### **Method of measurement**

Determining the ease of separation score by observation based on scoring from 1 to 4 according to the table from 1 to 4, respectively: unafraid and cooperative - slight fear or crying quiet with assurance - moderate fear, crying not quiet with assurance - crying, need for restraint

### 3

#### **Description**

Acceptance of drug

#### **Timepoint**

When inducing anesthesia inside the operating room

#### **Method of measurement**

Children are transported into the operating room and then inhaled anesthesia with a mask is induced in all groups using soufflore gas (4-8%). The acceptance rate of induction of anesthesia is determined based on the scoring of the table. Respectively from 1 to 3: refused to accept - accept with difficulty - accept without complaining

## **Secondary outcomes**

### 1

#### **Description**

Mean blood pressure

#### **Timepoint**

Under monitoring from 30 minutes before anesthesia, every 5 minutes from the time of sedation until induction of anesthesia, every 15 minutes throughout the operation and in recovery until full awakening, re-measured in case of side effects up to 24 hours after

surgery.

#### **Method of measurement**

arm sphygmomanometer In millimetres of mercury

### 2

#### **Description**

Heart rate

#### **Timepoint**

Under monitoring from 30 minutes before anesthesia, every 5 minutes from the time of sedation until induction of anesthesia, every 15 minutes throughout the operation and in recovery until full awakening, re-measured in case of side effects up to 24 hours after surgery.

#### **Method of measurement**

Cardiac monitoring and finger pulse oximetry

### 3

#### **Description**

Arterial oxygen saturation

#### **Timepoint**

Under monitoring from 30 minutes before anesthesia, every 5 minutes from the time of sedation until induction of anesthesia, every 15 minutes throughout the operation and in recovery until full awakening, re-measured in case of side effects up to 24 hours after surgery.

#### **Method of measurement**

Finger pulse oximetry

### 4

#### **Description**

Side effects (nausea and vomiting, hypotension, bradycardia)

#### **Timepoint**

In the postoperative period, patients will be monitored and followed for 24 hours for possible side effects.

#### **Method of measurement**

Nausea and vomiting with observation and examination - Hypotension (low blood pressure more than 20% of primary blood pressure) with arm sphygmomanometer - Bradycardia (heart rate less than 70 beats per minute) with heart monitoring and finger pulse oximetry

### 5

#### **Description**

Time to get Aldrete Score 8 and above

#### **Timepoint**

One turn (after the end of the operation until reaching the Aldrete score 8 and above)

#### **Method of measurement**

In minutes from the end of the operation until reaching the Aldrete score of 8 and above In the recovery room according to the table The Modified Aldrete Postanesthesia Score in pediatric

## **Intervention groups**

## 1

### Description

Intervention group: The first group: midazolam half mg / kg (midazolam ampoule made by Caspian Tamin Company Rasht - Iran) after calculating the amount of drug based on the weight of the child, to equalize and create an acceptable taste of one ml of 20% dextrose solution to the intervention drug is calculated Is added for each patient, and finally, to match the groups, the volume of the prescribed substance with distilled water is increased to 5 ml, and by the intern, who is unaware of the type of drug prescribed, it is poured into the syringes containing the intervention drug under the child's tongue. To be swallowed with a little pause in the mouth.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: The second group: Ketamine 5 mg/kg (ketamine consumed by Rotex Medica - Germany) after calculating the amount of drug based on the weight of the child, to equalize and create an acceptable taste of one ml of 20% dextrose solution to the intervention drug is calculated Is added for each patient, and finally, to match the groups, the volume of the prescribed substance with distilled water is increased to 5 ml, and by the intern, who is unaware of the type of drug prescribed, it is poured into the syringes containing the intervention drug under the child's tongue. To be swallowed with a little pause in the mouth.

### Category

Treatment - Drugs

## 3

### Description

Intervention group: The third group: Dexmedetomidine 4 micrograms per kilogram orally (dexmedetomidine made by Elixir Company - Iran) after calculating the amount of drug based on the weight of the child, to equalize and create an acceptable taste of one ml of 20% dextrose solution to the intervention drug is calculated Is added for each patient, and finally, to match the groups, the volume of the prescribed substance with distilled water is increased to 5 ml, and by the intern, who is unaware of the type of drug prescribed, it is poured into the syringes containing the intervention drug under the child's tongue. To be swallowed with a little pause in the mouth.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Vali-ye-Asr Hospital of Arak

##### Full name of responsible person

Hesameddin Modir

#### Street address

Vali-ye-Asr Hospital of Arak, Hazrat Valiasr Square

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Arak

#### Province

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#### Phone

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## 2

#### Recruitment center

##### Name of recruitment center

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#### Recruitment center

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Hesameddin Modir

**Position**

Associate Professor of Anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

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**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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Medical Intern

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A Level or less

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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**

Yes - There is 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**

After the publication of the article, confidential information such as patient and hospital details, etc. will be deleted and other information will be provided to researchers.

### **When the data will become available and for how long**

After publishing the article

### **To whom data/document is available**

Medical specialists

### **Under which criteria data/document could be used**

Medical professionals can access the data for research purposes.

### **From where data/document is obtainable**

Email the corresponding author

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

Official and academic email to the corresponding author

### **Comments**