

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

#### Protocol summary

##### Study aim

A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

##### Design

This study is clinical trials and double blind.153 patients candidated elective surgery with 2 to 10 years in hospitals affiliated to Arak University of Medical Sciences will enter.

##### Settings and conduct

This study is clinical trials and double blind.153 patients candidated elective surgery with 2 to 10 years in hospitals affiliated to Arak University of Medical Sciences will enter.The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 2 to 10 years, no history of allergies Dexmedetomidine and Midazolam and Melatonin, the absence of liver, kidney, heart and lung disorders, no use long-term anti seizure drug, lack of sleep disorder, lack of digestive disorders Exclusion criteria: Dissatisfied to participate in the study

##### Intervention groups

We divide patients in 3 groups randomly.We prescribe 0/5 milligram in kilogram in first group, 0/2 milligram in kilogram in second group and 2/5 micro gram in kilogram in third group.

##### Main outcome variables

pediatric sedation and ease of separation from their parents before anesthesia

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141209020258N77**

Registration date: **2018-05-18, 1397/02/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

#### Registration date

2018-05-18, 1397/02/28

#### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-03-11, 1396/12/20

#### Expected recruitment end date

2020-03-10, 1398/12/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A Comparative study between midazolam

,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

### Public title

A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

2 to 10 years No history of allergies Dexmedetomidine and Midazolam and Melatonin The absence of liver, kidney, heart and lung disorders No use long-term anti seizure drug Lack of sleep disorder Lack of digestive disorders

#### Exclusion criteria:

Dissatisfied to participate in the study

### Age

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

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **153**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization with random numbers

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee Arak University Of Medical Sciences

##### Street address

Vice chancellor for research, Payambar azam

complex, Basij square, Sardasht, Arak

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Approval date

2018-03-04, 1396/12/13

#### Ethics committee reference number

IR.ARAKMU.REC.1396.313

## Health conditions studied

### 1

#### Description of health condition studied

sedation

#### ICD-10 code

T88.52

#### ICD-10 code description

Failed moderate sedation during procedure

## Primary outcomes

### 1

#### Description

separation from their parents

#### Timepoint

Before surgery

#### Method of measurement

separation score

### 2

#### Description

sedation score

#### Timepoint

Before prescribing drugs, then when the child is separated from the parent

#### Method of measurement

sedation score

### 3

#### Description

blood pressure

#### Timepoint

every 5 minute in surgery

#### Method of measurement

Barometer

### 4

#### Description

heart rate

#### Timepoint

every 5 minute in surgery

#### Method of measurement

beat in minute

## 5

### Description

Percent saturation of oxygen

### Timepoint

every 5 minute in surgery

### Method of measurement

Percent

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: We prescribe 0/5 milligram in kilogram

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: We prescribe 0/2 milligram in kilogram .

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: We prescribe 2/5 micro gram in kilogram .

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkabir hospital

##### Full name of responsible person

Dr Bijan Yazdi

##### Street address

Parastar square, Shahid Shirodi street

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

yazdi@arakmu.ac.ir

## 2

### Recruitment center

### 3

#### Recruitment center

##### Name of recruitment center

Valiasr hospital

##### Full name of responsible person

Dr Bijan Yazdi

##### Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3222 2003

##### Email

yazdi@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Vice chancellor for research, Payambar azam complex, Basij squire, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

arjmandzadegan@arakmu.ac.ir

#### 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**  
Dr Hesamedin Modir  
**Position**  
Assistante professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Valiasr Hospital, Valiasr squire, Shahid Shirodi street  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Email**  
modir.he@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
dr Bijan Yazdi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Valiasr Hospital, Valiasr squire, Shahid Shirodi street  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
yazdi@arakmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mahsa Mombini  
**Position**  
student of medicine  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Payambar azam complex, Basij squire, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Email**  
m.m137190@gmail.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

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

When we publish article in journal.

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

After the article is published

### To whom data/document is available

researcher in university

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

If there are additional questions

### From where data/document is obtainable

Dr Bijan Yazdi

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

They have to write letters to the professors and the university

### Comments