

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comparison of Dexmedetomidine- Ketamin and Fentanyl-Ketamin in sedation and analgesia in cystoscopy

#### Protocol summary

##### Study aim

Comparison of Dexmedetomidine- Ketamin and Fentanyl-Ketamin in sedation and analgesia in cystoscopy

##### Design

This double-blind and clinical trial .60 patients who are candidates for cystoscopy at Valiasr Hospital in Arak.

##### Settings and conduct

This double-blind and clinical trial will be conducted on 60 patients who are candidates for cystoscopy at Vali Asr Hospital in Arak. The patients are divided into two groups by simple randomization with random number table. This study is clinical trial. Outcome evaluator and analyzer and participant are blind (double blind). Assessor and analyzer and participant are not aware of group allocation

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Both gender, age 18 to 65 years old, ASA Class 1 and 2, cystoscopy candidate, no allergy to used drugs, no history of cardio-pulmonary-liver and kidney disease, lack of Obstructive Sleep Apnea (OSA), no history of drug addiction or other psychotropic substances, no history of use of drug or alcohol, no history of psychological illness  
Exclusion criteria: lack of consent

##### Intervention groups

Dexmedetomidine and ketamine: We inject 0.5 milligram in kilogram Ketamin and 1 milligram in kilogram of Dexmedetomidine. The Fentanyl and Ketamine: We inject 0.5 milligram in kilogram Ketamin and fentanyl 2 micro gram in kilogram.

##### Main outcome variables

Duration of cystoscopy-pain-satisfaction-scrob-rumsy-mean arterial blood pressure-heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N105**

Registration date: **2019-04-21, 1398/02/01**

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

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

##### Registration date

2019-04-21, 1398/02/01

##### 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

2018-07-02, 1397/04/11

##### Expected recruitment end date

2019-07-02, 1398/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Dexmedetomidine- Ketamin and Fentanyl-Ketamin in sedation and analgesia in cystoscopy

##### Public title

Comparison of Dexmedetomidine- Ketamin and Fentanyl- Ketamin in analgesia in cystoscopy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Both sexes Age 18 to 65 years old ASA Class 1 and 2  
Cystoscopy candidate No allergy to used drugs No history of cardio-pulmonary-liver and kidney disease  
Lack of Obstructive Sleep Apnea (OSA) No history of drug addiction or other psychotropic substances No history of acute drug or alcohol poisoning No history of psychological illness

### Exclusion criteria:

Dissatisfaction to participate in the study

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple random number table

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is clinical trial. Outcome evaluator and analyzer and participant are blind (double blind). Outcome evaluator and analyzer and participant don't aware from grouping.

## 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

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

## Province

Markazi

## Postal code

848176941

## Approval date

2018-07-02, 1397/04/11

## Ethics committee reference number

IR.ARAKMU.REC.1397.108

## Health conditions studied

### 1

#### Description of health condition studied

cystoscopy

#### ICD-10 code

#### ICD-10 code description

cystoscopy

## Primary outcomes

### 1

#### Description

Duration of cystoscopy

#### Timepoint

After intervention

#### Method of measurement

hours

### 2

#### Description

pain

#### Timepoint

Every 5 minutes to 60 minutes

#### Method of measurement

Visual analog scale

### 3

#### Description

relaxation

#### Timepoint

Initially and after analgesia, and every 5 minutes during the procedure until 60 minutes later

#### Method of measurement

Ramsy score

### 4

#### Description

satisfaction

#### Timepoint

After intervention

#### Method of measurement

questionnaire

### 5

#### Description

mean arterial blood pressure

### Timepoint

Every 5 minutes after the start of anesthesia until the end of the cystoscopy and during recovery

### Method of measurement

mmHg

## 6

### Description

heart rate

### Timepoint

Every 5 minutes after the start of anesthesia until the end of the cystoscopy and during recovery

### Method of measurement

count

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Dexmedetomidine and ketamine: We inject 0.5 milligram in kilogram Ketamin and 1 milligram in kilogram of Dexmedetomidine.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: The Fentanyl and Ketamine: We inject 0.5 milligram in kilogram Ketamin and fentanyl 2 micro gram in kilogram.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr Hospital

##### Full name of responsible person

Dr Hesamedin Modir

##### Street address

Valiasr hospital, Valiasr square

##### City

Arak

##### Province

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##### Postal code

848176941

##### Phone

+98 86 3222 2003

##### Email

modir.he@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

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##### Postal code

848176941

##### Phone

+98 86 3222 2003

##### Email

modir.he@gmail.com

#### 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 Esmaeel Moshiri

##### Position

Assistant

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Shahid Shirodi street, Valiasr square, Valiasr hospital

##### City

Arak

##### Province

Markazi

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3814957558

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modir.he@gmail.com  
**Web page address**

## Person responsible for scientific 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  
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modir.he@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Tanaz Kamalpour  
**Position**  
Assisstant professor  
**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Payambar Azam Complex, Basij square, Sardasht, Arak  
**City**  
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**Province**  
Markazi  
**Postal code**  
848176941  
**Phone**  
+98 86 3222 2003  
**Email**  
Kamalpour@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 Modir

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

They have to write letters to the professors and the university

### Comments