

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-scrub-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)

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+98 86 3222 2003

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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

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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

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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

Dr Esmaeel Moshiri

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity
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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

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