

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison effect of Diphenhydramine-propofol versus ketamine-propofol in improving the quality of deep sedation in male patients undergoing rigid cystoscopy

Protocol summary

Study aim

Comparison of the effect of diphenhydramine-propofol and ketamine-propofol on sedation and analgesia for male cystoscopy

Design

A double-blind clinical trial study of 100 male patients who are candidates for cystoscopy at Sina Hospital in Tehran.

Settings and conduct

This double-blind and clinical trial will be conducted on 100 male patients who are candidates for cystoscopy at Sina Hospital in Tehran. The patients are divided into two groups by Block balanced randomization. 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: male patients, age 20 to 75 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

Diphenhydramine and propofol group: 0.6 mg / kg diphenhydramine and 0.6 mg / kg propofol. Ketamine and propofol group: 0.5 mg / kg ketamine and 0.6 mg / kg propofol. Receive.

Main outcome variables

Duration of cystoscopy - Pain intensity - Patient and surgeon satisfaction - Depth of sedation - Total propofol consumption changes in mean Arterial blood pressure - changes in Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130304012695N12**

Registration date: **2022-05-03, 1401/02/13**

Registration timing: **prospective**

Last update: **2022-05-03, 1401/02/13**

Update count: **0**

Registration date

2022-05-03, 1401/02/13

Registrant information

Name

mohammadreza khajavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1220

Email address

khajavim@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Diphenhydramine-propofol versus ketamine-propofol in improving the quality of deep sedation in male patients undergoing rigid cystoscopy

Public title

Comparison of the effect of diphenhydramine propofol with ketamine propofol on analgesia in male patients under cystoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

male patient Age 20 to 75 years old Cystoscopy candidate ASA Class 1 and 2 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:

History of closed glaucoma History of dry mouth disease

Age

From **20 years** old to **75 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize patients with inclusion criteria Block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

Blinding (investigator's opinion)

Double blinded

Blinding description

To randomize patients with inclusion criteria Block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Sina hospital; Hasan Abad square; Emam khomeni street

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-05-02, 1401/02/12

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1401.014

Health conditions studied

1

Description of health condition studied

Cystoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of Cystoscopy

Timepoint

Once .Start and end of Cystoscopy

Method of measurement

With stopwatch

2

Description

Mean Arterial Blood Pressure

Timepoint

Before the cystoscope enters the urethra and bladder, 30 seconds after entering the urethra, then every 2 minutes

Method of measurement

Non-invasive and automatically

3

Description

Heart Rate

Timepoint

Before the cystoscope enters the urethra and bladder, 30 seconds after entering the urethra, then every 2 minutes

Method of measurement

from monitor

4

Description

The amount of propofol consumed

Timepoint

Once at the end of cystoscopy

Method of measurement

In milligrams

5

Description

Patient response when a cystoscope enters the urethra

Timepoint

When the cystoscope enters the urethra

Method of measurement

Observe the patient's movements and rate it from 0-3 according to the type of movements

6

Description

pain intensity

Timepoint

During cystoscopy and in recovery

Method of measurement

visual analog scale (VAS)

7

Description

Quality and satisfaction of the surgeon from Sedition

Timepoint

At the end of cystoscopy

Method of measurement

Ask the surgeon and score from 1-4

8

Description

Quality and patient satisfaction from sedation

Timepoint

in recovery room

Method of measurement

Ask the patients and score from 1-4

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, midazolam was injected 0.03 mg / kg, fentanyl 2µ /kg intravenously, then patients in the Diphenhydramine group received 0.6 mg / kg diphenhydramine intravenously. Propofol 0.5 mg / kg is injected 3 minutes after injection of these drugs and 60 seconds before the start of cystoscopy. Then the quality of sedation, pain and hemodynamic changes are examined during cystoscopy. In case of pain and movements that indicate the patient's intolerance, propofol is injected again to calm the patient.

Category

Treatment - Drugs

2

Description

Control group: First, midazolam was injected 0.03 mg / kg, fentanyl 2µ /kg intravenously, then patients in the Ketamine group received 0.6 mg / kg ketamine intravenously. Propofol 0.5 mg / kg is injected 3 minutes after injection of these drugs and 60 seconds before the start of cystoscopy. Then the quality of sedation, pain and hemodynamic changes are examined during cystoscopy. In case of pain and movements that indicate the patient's intolerance, propofol is injected again to calm the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sina Hospital

Full name of responsible person

Mohammad Reza Khajavi

Street address

Sina Hospital Imam khomeini st

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khajavim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

City

Tehran

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1417653761

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vcr@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research, Tehran University of Medical Sciences

Proportion provided by this source

50

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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khajavi

Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

Main study outcome data

When the data will become available and for how long

Six months after the end of the study

To whom data/document is available

University researchers

Under which criteria data/document could be used

Share experiences to increase the knowledge

From where data/document is obtainable

khjavim@tums.ac.ir Dr.khajavi

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

Through Dr. Khajavi e-mail address: khjavim@tums.ac.ir

Comments