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 elevator 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
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Sina Hospital Imam khomeini st
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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.
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1417653761
Phone
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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
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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Postal code
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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
khajavim@tums.ac.ir Dr.khajavi
What processes are involved for a request to access data/document
Through Dr. Khajavi e-mail address: khajavim@tums.ac.ir
Comments