

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of hemodynamic changes of dexmedetomidine in comparison with ketamine in patients undergoing colonoscopy under sedation with propofol

Protocol summary

Study aim

Using the results of this study to reduce the dose of propofol and use dexmedetomidine and reduce respiratory complications in patients and reduce recovery time

Design

The clinical trial with control group, with parallel, double-blind, randomized, phase 3 groups on 70 patients, patients with simple randomization of quadruple permutation block will be divided into the first and second groups that the first group receive propofol, intravenous ketamine and the second group will receive propofol and dexmedetomidine.

Settings and conduct

. Outpatient colonoscopy patients referred to Imam Khomeini Hospital in Ahvaz will be divided into two groups .The present study is two-blind so that patients and physicians will be unaware of the allocation of both groups.

Participants/Inclusion and exclusion criteria

No cardiovascular disease, renal or liver failure, no drug addiction, no dexmedetomidine contraindications, propofol, which are classified in class 1 and 2 of the American Society of Anesthesiology), and II,I class ASA) are selected.

Intervention groups

The first group will be given propofol with a dose of 0.5mg per kg and dexmethomidine at a dose of 1 mg per kg at a rate of 0.5 mg per kg per hour, and the second group will be given propofol at a dose of 0.5 mg per kg and ketamine at a dose of 0.5 mg per kg.

Main outcome variables

Sedation rate, hemodynamic instability, drug level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220706055402N1**
Registration date: **2022-08-01, 1401/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-01, 1401/05/10**

Update count: **0**

Registration date

2022-08-01, 1401/05/10

Registrant information

Name

Fatemeh Moftakhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3338 3372

Email address

moftakhar-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-20, 1401/04/29

Expected recruitment end date

2022-08-10, 1401/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of hemodynamic changes of

dexmedetomidine in comparison with ketamine in patients undergoing colonoscopy under sedation with propofol

Public title

dexmedetomidine in colonoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The absence of cardiovascular diseases The absence of kidney or liver failure diseases absence of drug addiction absence of contraindications to the use of dexmedetomidine, propofol people which are classified in class 1 and 2 of the American Society of Anesthesiology (II, I class ASA) are selected.

Exclusion criteria:

Unwillingness of the patient to participate in the study intestinal perforation during procedure bleeding of the esophagus or stomach or intestine during the procedure changing the type of procedure during colonoscopy or requiring surgery during the procedure

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the classification of the subjects is done by the four-point permutation block method. In this method, A represents the person who receives the intervention and B represents the person who is placed in the control group. Code 1, abba code 2, BAAB code 3, BBAA code 4 and BABA code 5 to 9. 21 Numbers are considered as rows or columns. 138 people will be divided into two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, the participants in the study, the endoscopic physician and the principal investigator are not aware of the allocation method and the drugs are injected by an anesthesiologist who is aware of the allocation and the data collection is done by them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan Educational-Research and Treatment Center of Ahvaz Jundishapur University

Street address

Golestan hospital, Golestan Ave, Golestan town

City

Ahvaz

Province

Khuzestan

Postal code

6135733118

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.048

Health conditions studied

1

Description of health condition studied

colonoscopy, sedation

ICD-10 code

T88.52

ICD-10 code description

Failed moderate sedation during procedure

Primary outcomes

1

Description

Total amount of Propofol consumed

Timepoint

From start to end of colonoscopy

Method of measurement

Dose of drug

2

Description

Level of sedation

Timepoint

From start to end of colonoscopy

Method of measurement

Ramsay Sedation Scale

3

Description

Amount of pain

Timepoint

From start to one hour after colonoscopy

Method of measurement

Visual Analogue Scale

4

Description

Amount of Nausea and Vomiting

Timepoint

From start to end of colonoscopy

Method of measurement

Visual Analogue Scale

5

Description

Time of recovery

Timepoint

From start to end of colonoscopy

Method of measurement

From end of colonoscopy to full consciousness

6

Description

Hemodynamic instability

Timepoint

From start to end of colonoscopy

Method of measurement

Amount of Heart rate, mean arterial pressure and blood oxygen saturation changes

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will use propofol with a dose of 0.5 mg per kg and dexmedetomidine with a dose of 1 mg per kg and at a rate of 0.5 mg per kg per hour manufactured by Daro Farah Iran Company

Category

Treatment - Drugs

2

Description

Intervention group: Propofol is given at a dose of 0.5 mg per kg and ketamine at a dose of 0.5 mg per kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam khomeini Hospital

Full name of responsible person

Reza Akhondzadeh

Street address

Imam Khomeini hospital, Azadegan street

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3292 3985

Email

rezaakh@hotmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Ahvaz University of medical science, Golestan street, Golestan town

City

Ahvaz

Province

Khouzestan

Postal code

06133110000

Phone

+98 61 3336 2414

Email

itc@ajums.ac.ir

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Moftakhar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital,Azadegan St,Ahwaz

City

Ahwaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3338 3372

Fax

Email

moftakhar-f@ajums.ac.ir

Person responsible for scientific inquiries

Contact

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Contact

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Ahvaz University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After the study will be determined

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available