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 dexmedtomidine 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 dexmedtomidine.

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 dexmedomidine 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)

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+98 61 3338 3372

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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 Universi
Street address
Golestan hospital,Golestan Ave,Golestan town
City
Ahvaz
Province
Khouzestan
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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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