Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of dexmedetomidine with intravenous lidocaine in patients undergoing colonoscopy under sedation with propofol-fentanyl

Protocol summary

Study aim
Comparison of the effect of dexmedetomidine with intravenous lidocaine in patients undergoing colonoscopy under sedation with propofol-fentanyl

Design
This study is a double-blind clinical trial that will be conducted with parallel and randomized groups on 120 patients.

Settings and conduct
This study was conducted at Imam Khomeini Hospital in Ahvaz and is double-blind. 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.

Participants/Inclusion and exclusion criteria
The inclusion criteria conditions include candidates for colonoscopy who need anesthesia, are between the ages of 18 and 65, do not suffer from cardiovascular diseases, kidney or liver failure. Exclusion criteria include the patient's unwillingness to participate in the study, intestinal perforation during the procedure, esophageal or stomach or intestinal bleeding during the procedure, changing the type of procedure during colonoscopy, or the need for surgery during the procedure.

Intervention groups
In the case group, intravenous lidocaine was injected with an initial dose of 1.5 mg/kg and a maintenance dose of 1 mg/kg/h, plus propofol 0.5 mg/kg and 1 microgram/kg of fentanyl. In the control group, dexmedetomidine was injected with an initial dose of 1 µg/kg and a maintenance dose of 0.5 µg/kg per hour in addition to propofol 0.5 mg/kg and fentanyl 1 µg/kg.

Main outcome variables
sedation; pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220706055402N2**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-11, 1401/11/22**
Update count: **0**

Registration date
2023-02-11, 1401/11/22

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
2023-01-21, 1401/11/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of dexmedetomidine with intravenous lidocaine in patients undergoing colonoscopy under sedation with propofol-fentanyl

Public title
dexmedetomidine with intravenous lidocaine in colonoscopy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Colonoscopy candidate patients who need anesthesia In the age range of 18 to 65 years Not suffering from cardiovascular diseases, kidney or liver failure No drug addiction Patient willingness to participate in the study

Exclusion criteria:
The patient's unwillingness to participate in the study Intestinal perforation during the procedure Esophageal or stomach or intestinal bleeding during the procedure Changing the type of procedure during colonoscopy or the need for 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: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
With the easy sampling method, the referring people who are eligible to enter the study are randomly divided into two intervention and control groups. In this study, the division of people is done by the four permutation block method. In this method, A represents an individual. is the one who receives the intervention and B represents the person who is placed in the control group. Considering the block of four, replace AABB with code 0, replace ABAB with code 1, replace ABBA with code 2, replace BAAB with code 3, replace with BBAA code 4 and BABA we give the code 5 to 9. Then, using the table of random numbers, we randomly choose a starting point and after that we consider 21 numbers in a row or column. Considering the order of the numbers in the table, for each We will replace the corresponding number with the number we found. Finally, by selecting 21 numbers from the table of allocation, the total of 120 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
2022-12-13, 1401/09/22

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.156

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
Level of sedation

Timepoint
From start to end of colonoscopy

Method of measurement
Ramsay Sedation Scale

2

Description
Amount of pain

Timepoint
From start to one hour after colonoscopy

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous lidocaine is injected with an initial dose of 1.5 mg/kg and a maintenance dose of 1 mg/kg/h, in addition to propofol 0.5 mg/kg and 1 microgram/kg of fentanyl.
Category
Treatment - Drugs

2

Description
Intervention group: Dexmedetomidine is injected with an initial dose of 1 µg/kg and a maintenance dose of 0.5 µg/kg per hour, plus propofol 0.5 mg/kg and fentanyl 1 µg/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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
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Ahvaz University of medical science,Golestan street,Golestan town
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06133110000
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itc@ajums.ac.ir
Grant name
Ahvaz University of Medical Sciences
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)
Undecided - It is not yet known if there will be a plan to make this available
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