

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)

Phone

+98 61 3338 3372

Email address

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 University

Street address

Golestan hospital, Golestan Ave, Golestan town

City

Ahvaz

Province

Khuzestan

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

City

Ahvaz

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Khouzestan

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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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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

Street address

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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