

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

A Comparison between the effect of Propofol Fentanyl and Propofol Ketamine on Colonoscopy patients' sedation.

Protocol summary

Study aim

A Comparison between the effect of Propofol Fentanyl and Propofol Ketamine on Colonoscopy patients' sedation.

Design

The clinical trial has two intervention groups, with parallel, double-blind groups randomized on 144 patients, 72 people in each group. Randomization is based on 4 random shifts.

Settings and conduct

After connecting the monitors to the patients in both groups, first the basic vital signs including systolic and diastolic blood pressure, heart rate and blood oxygen saturation percentage are measured and recorded in the questionnaire form. In the first intervention group, 0.5 mg per each kg of Propofol and 0.5 mg per each kg of Ketamine are injected before the procedure. In the second intervention group, 0.5 mg per each kg of Propofol and 1 µg per each kg of Fentanyl are injected before the procedure as well. Then the amount of sedation is measured based on Ramsay score and the amount of patient pain is measured based on Ambesh score at the beginning of the procedure, the end of the procedure and one hour after the end of the procedure.

Participants/Inclusion and exclusion criteria

Patients in the age range of 18 to 65 years, with classification of Group 1 and 2 American Society of Anesthesiologists (ASA Class I & II), are selected as inclusion criteria. As exclusion criteria all patients with drug allergy, age less than 18 or more than 65 years, Kidney or liver failure, people with chronic pain syndromes, the patient's unwillingness to participate in the study, drug addiction, patients with cardiovascular, respiratory, metabolic and neurological diseases, airway problems, ASA class three or four and having a contraindication to Propofol Ketamine or Propofol Fentanyl are excluded from the study.

Intervention groups

In the first intervention group, Propofol Ketamine and in

the second intervention group, Propofol Fentanyl is used.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048445N1**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Maryam Hosseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3376 5834

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A Comparison between the effect of Propofol Fentanyl and Propofol Ketamine on Colonoscopy patients' sedation.

Public title
A Comparison between the sedative effect of Fentanyl and Ketamine outside the operating room.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
They are between 18 and 65 years old Patients are referred for colonoscopy procedure Classification of Group 1 and 2 American Society of Anesthesiologists (ASA Class I & II) are selected as inclusion criteria.
Exclusion criteria:
the patient's unwillingness to participate in the study They are under 18 years old They are over 65 years old They have kidney failure They have liver failure They have chronic pain syndrome They are addicted They have any drug allergies They have cardiovascular disease They have a respiratory disease They have metabolic diseases They have a neurological disease They have difficult airways The patient is classified as ASA class 3 and 4 Contraindicated propofol ketamine or propofol fentanyl

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects were randomly divided into two groups based on the method of four random blocks. The site www.sealedenvelope.com was used for randomization. If we call the two groups A and B, the logic of randomization is that we select as many samples from the 6 blocks, AAB, BAAB, BBAA, ABBA, ABAB and BABA, by (ie as n / 4) by placing them to reach the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to double blind the study, the patient's degree of sedation is recorded according to a modified Ramsay standard during the procedure by another person who does not know the medication prescribed to the patient.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan Hospital, Golestan BLVD

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.AJUMS.REC.1399.043

Health conditions studied

1

Description of health condition studied

Pain management of patients referred for Colonoscopy and reduce their anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

A score of 5 or 6 RAMSAY criteria in the questionnaire. RAMSAY sedation criteria including 6 scores is as follows:
1. Completely awake and anxious
2. Quiet and calm with enough cooperation
3. Asleep and wakes up with a verbal command
4. Asleep and woke up with mild stimulation, but gives a strong reaction to painful stimuli
5. Slow reaction to painful stimuli
6. Lack of reaction to painful stimuli.

Timepoint

5 minutes after the procedure, 10 minutes after the procedure, 15 minutes after the procedure.

Method of measurement

Verbal measurement criteria

Secondary outcomes

1

Description

The amount of pain

Timepoint

Start of procedure , end of procedure and one hour after the end of the procedure

Method of measurement

The Ambesh criterion, which includes the following four-point grading questions: 1. No pain: Negative answer to questions about having pain 2. Mild: Positive answers to questions about having pain, but without any physical symptoms 3. Medium: Positive answers to questions about having pain and the appearance of physical symptoms or successive complaints of pain 4. Intensity: The patient verbally complains of severe pain or shows pain with frowning and upset in the face or turning away with hand or expressing fear.

2

Description

Recovery time

Timepoint

Recovery time is defined as fast (less than 5 minutes), medium (between 5 to 10 minutes) and slow (more than 15 minutes).

Method of measurement

Patient's appropriate answers to questions

3

Description

Nausea

Timepoint

Every 5 minutes

Method of measurement

It is expressed by the person herself/himself

4

Description

Systolic blood pressure

Timepoint

Every 5 minutes

Method of measurement

Blood pressure monitor

5

Description

Diastolic blood pressure

Timepoint

Every 5 minutes

Method of measurement

Blood pressure monitor

6

Description

heart beat

Timepoint

every 5 minutes

Method of measurement

Cardiac monitor

7

Description

Arterial blood oxygen saturation

Timepoint

Every 5 minutes

Method of measurement

Respiratory monitor

Intervention groups

1

Description

The first intervention group: The group receiving Propofol Fentanyl for sedation during Colonoscopy.

Category

Treatment - Drugs

2

Description

Intervention group 2: The group receiving Propofol Ketamine for sedation during Colonoscopy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Reza Baghbanian

Street address

No.1519 , Shahid Ahvazian Ave, Azadegan St. Ahvaz
Imam Khomeini Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Baghbanian

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No 123/1 , 3d Phase , West Mordad St, Chamran Blvd

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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

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

Baghbanian reza

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Baghbanian reza

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hosseinpour Maryam

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

The Excel file contains the identification code, reference to the file number and the registered information, except for the documents that can be provided.

When the data will become available and for how long

6 months after printing the results until 10 years later

To whom data/document is available

All those who officially correspond with the Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Under which criteria data/document could be used

Documents can be used for systematic review studies and meta-analysis

From where data/document is obtainable

Vice Chancellor for Research Ahvaz Jundishapur University

What processes are involved for a request to access data/document

After approval from the Vice Chancellor for Research, the data file will be provided to the Vice Chancellor and then the data will be shared with other researchers or emailed to them.

Comments

The material and intellectual property of this project is with Ahvaz University of Medical Sciences