

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of analgesic effects of oral oxycodone and intravenous fentanyl in patients undergoing lower gastrointestinal colonoscopy

Protocol summary

Study aim

Determination of analgesic effect of oral oxycodone and intravenous fentanyl in patients undergoing colonoscopy

Design

A randomized, double-blind, three-phase, randomized clinical trial performed on 80 patients at random.

Settings and conduct

The studied population are patients aged 18-69 years who are candidates for colonoscopy, referring to Ayatollah Rohani Medical Training Center of Babol. The patients are randomly divided into two intervention groups using the random number table method and the intervention is performed on them.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Consent to participate in the study; colonoscopy candidate; The American Society of Anesthesiologists (ASA) class I&II and Age 18-69 years old
Exclusion Criteria: Decreased level of consciousness GCS less than 15; History of drug addiction; Hemodynamic instability and Mental disorder

Intervention groups

Intervention group: patients receive slow-release oral oxycodone (Faroxi company) with a dose of 30 mg one hour before the start of the colonoscopy, then enter the room after one hour, and after monitoring and 5 minutes before the start of the colonoscopy, one cc Normal intravenous saline is prescribed. Control group: patients receive placebo capsules one hour before the start of colonoscopy, then enter the room after one hour, and after entering the room and monitoring, they receive 50 micrograms of intravenous fentanyl (Caspian) (one cc). 0.5 to 1 ml per body weight of propofol (Caspian Company) was administered intravenously to both groups.

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111010007752N13**

Registration date: **2022-10-14, 1401/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-14, 1401/07/22**

Update count: **0**

Registration date

2022-10-14, 1401/07/22

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

Email address

pamrimaleh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2023-03-30, 1402/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effects of oral oxycodone and intravenous fentanyl in patients undergoing lower gastrointestinal colonoscopy

Public title

Analgesic effect of oral oxycodone and intravenous fentanyl in patients undergoing colonoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The American Society of Anesthesiologists (ASA) class I&II (Grade 1: No cardiovascular, respiratory, glandular and Grade 2: Controlled diabetes) Age 18-69 years old Colonoscopy candidate Consent to participate in the study

Exclusion criteria:

Decreased level of consciousness GCS less than 15
History of drug addiction Hemodynamic instability Mental disorders

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using permuted blocks of size 4. (AABB) in such a way that blocks of 4 consist of random combinations of 2 A (Oxycodone) and 2 B (Fentanyl). It will be allocated to two groups of 40 people. Creating a random sequence in the blocks will be done by a statistician.

Blinding (investigator's opinion)

Double blinded

Blinding description

Oxycodone is in capsule form. For the purpose of blinding, capsules containing placebo are chosen to be the same shape as oxycodone capsules, so that they are completely similar in terms of smell, color and shape. Capsules containing oxycodone and placebo are placed in cans of the same shape and size, and then a code will be written on each can. After the patient enters the study, one of these cans will be assigned to the patient and the code on the can will be written on the patient's file (study checklist), while the researcher does not know the contents of the can and the codes. Opening the codes will be done after completing the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.MUBABOL.REC.1401.084

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

intensity of pain

Timepoint

during colonoscopy

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive slow-release oral oxycodone (Faroxi company) with a dose of 30 mg one hour before the start of the colonoscopy, then after one hour they enter the room, and after monitoring and 5 minutes before the start of the colonoscopy, 1 cc Normal saline intravenous saline is prescribed.

Category

Treatment - Drugs

2**Description**

Control group: patients receive placebo capsules one hour before the start of colonoscopy, then enter the room after one hour, and after entering the room and monitoring, they receive 50 micrograms of intravenous fentanyl (Caspian) (1 cc).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rouhani Hospital

Full name of responsible person

Parviz Amri

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Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

mehdi rajabnia

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Parviz Amri

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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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

There is still no plan for its publish

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