Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of Oxycodone and Mebeverin mixed-effects on colonoscopy quality in patients referring to Urmia Imam Khomeini hospital

Protocol summary

Study aim
Determining the combined effect of oxycodone and Mebeverine on colonoscopy quality in patients referred to Imam Khomeini Hospital

Design
Clinical trial with control group, with parallel groups, double-blind, randomized by random number table, phase three on 125 patients.

Settings and conduct
125 people referring to the colonoscopy ward of Imam Khomeini Educational and Medical Center in Urmia, if they have inclusion criteria and do not have exclusion criteria. after the randomization by the table of lucky numbers and blinding so that if the number is out between 1 to 62 The patient will be in the intervention group and will receive the drug (oxycodone and Mebeverine) and if the number is between 63 to 125 will be in the control group and will receive the placebo (vitamin B6 tablets and starch capsules) one hour before colonoscopy.

Participants/Inclusion and exclusion criteria
Anyone over the age of 18 who is suspected of having intestinal polyps, unexplained gastrointestinal bleeding, and intestinal disease will undergo a colonoscopy with the inclusion criteria of do not take antispasmodics drugs, complete mental health for informed consent, insensitivity to oxycodone and Mebeverine and no history of abdominal surgery. Non-entry conditions: History of allergy to any type of drug and irritable bowel syndrome.

Intervention groups
In the intervention group, one oxycodone tablet and two Mebeverine capsules will be given to the patient one hour before colonoscopy by someone other than the endoscopist. In the control group, a vitamin B6 tablet will be given to the patient one hour before colonoscopy along with two starch-containing capsules.

Main outcome variables
Total procedure time, pain, time to reach the cecum

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201204049599N3**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **prospective**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Mohammad Reza Pashaee

Name of organization / entity

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Iran (Islamic Republic of)

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+98 44 3198 8001

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-30, 1400/02/10

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Assessment of Oxycodone and Mebeverin mixed-effects on colonoscopy quality in patients referring to Urmia Imam Khomeini hospital

Public title
Assessment of Oxycodone and Mebeverin mixed-effects on colonoscopy quality
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Do not take antispasmodics Suspicion of intestinal polyps bowel diseases Unknown gastrointestinal bleeding
Exclusion criteria:
Irritable Bowel Syndrome Previous abdominal surgeries Lack of mental health and full consciousness Allergy to oxycodone Allergy to Mebeverine Taking anti-anxiety and painkillers History of allergy to any drug
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **125**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method is simple randomization. the researcher will divide patients by using table of random numbers. First, each patient will be assigned a three-digit code according to the date and time of the clinic visit. The first patient will have code 001 and the last patient will have code 125. Then in the table of random numbers without looking, a location will be randomly selected. The first two digits will be examined. If the number is less than or equal to 125, it will be selected, otherwise we will continue moving in the direction of the line and other numbers will be checked. If it is a duplicate number, it will be ignored and another number from the table will be checked. We continue this process until 62 codes are selected. The first 62 codes will be for patients in the intervention group (patients who will receive drugs) and the remaining 63 codes will be for the control group (patients who will receive placebo). Thus, patients are randomly divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be two-way blind. The patient and the endoscopist will be unaware that the patient belongs to the case or control group. Pills and capsules in the same shape, size and color will be given to patients in both groups. In the intervention group, one oxycodone tablet, which is small and white, and two Mebeverine capsules, which are white, will be given to the patient one hour before colonoscopy by someone other than the endoscopist. In the control group, a vitamin B6 tablet, which is similar in shape, color and size to oxycodone and is completely safe, will be given to the patient one hour before colonoscopy, along with two starch-containing capsules that resemble Mebeverine capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences; Resalat boulevard
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2020-09-30, 1399/07/09
Ethics committee reference number
IR.UMSU.REC.1399.261

Health conditions studied

1

Description of health condition studied
colonoscopy
ICD-10 code
K92.2
ICD-10 code description
Gastrointestinal hemorrhage, unspecified

Primary outcomes

1

Description
Total procedure time
Timepoint
During endoscopy
Method of measurement
minute, clock

2

Description
pain
Timepoint
During endoscopy
Method of measurement
Score based on visual analog scale

3

Description
Time to reach Cecum
Timepoint
During endoscopy
Method of measurement
minute , clock

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One hour before colonoscopy, patients in this group will be given 15 mg of oral Oxycodone tablet and 270 mg of oral Mebeverine capsule .
Category
Treatment - Drugs

2

Description
Control group : In the control group, a vitamin B6 tablet, which is similar in shape, color and size to oxycodone and is completely safe, will be given to the patient one hour before colonoscopy, along with two starch-containing capsules that resemble Mebeverine capsules.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Pashaee
Street address
Imam Khomeini Hospital; Ershad boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
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Dr. Iraj Mohebbi
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Reza Pashaee
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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