Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of analgesic effect of intravenous paracetamol and fentanyl during colonoscopy: Prospective double blind clinical trial

Protocol summary

Summary

In a clinical trial, 60 patients 20 to 70 years old candidate for elective colonoscopy were randomly divided into two equal groups. Liver disease and addicted patients are excluded. The intervention group recieves Midazolam and Paracetamol (1gr in 100 cc of DW5%) for 30 min before colonoscopy and the control group recieves 100 mL of saline and midazolam and fentanyl. Dose and time of prescription drugs includs midazolam 0.5 mg/ kg (maximum 2.5 mg) and fentanyl 0.5 to 1 mg / kg three minuts before colonoscopy. To both groups, if the rescue dose is need, propofol 0.5 mg / kg as a bolus will administerd. Patients, anesthesiologists, Colonoscopist, and the patient's examiner are blinded. Depth of sedation (based on ramsay scale) Blood Pressure, Heart Rate, Respiratory Rate and Saturation of preferal oxigen is recorded since starting medication (every 5 minutes) until the patient is transferred to the recovery room. The onset of sedation (time 00:00) , the arrival time of colonoscopy , colonoscopy withdrawal from the anus , waking time (Aldret score equal or greater than 9)and the time of discharge readiness is measured by chronometer and recorded . Pain intensity based on the Visual Analogue Scale (0 to 10), nausea &vomiting during colonoscopy, recovery and 6 and 12 hours after colonoscopy is recorded . Hypotension , bradycardia during colonoscopy and delay in recovery and discharge (longer than 2 hours) is also recorded. Colonoscopist satisfaction after colonoscopy is investigated based on the Likert scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311227752N5**
Registration date: **2013-12-10, 1392/09/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-12-10, 1392/09/19

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Babol University of Medical sciences

Expected recruitment start date

2013-08-22, 1392/05/31

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intravenous paracetamol and fentanyl during colonoscopy: Prospective double blind clinical trial

Public title

Comparison of analgesic effect of intravenous paracetamol and fentanyl during colonoscopy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age 20-70 years; ASA class ≤ 3
Exclusion criteria: age <20 years or> 70 years; Heart disease (arrhythmias, Aortic Stenosis, Ischemic Heart Disease,Heart failure) ; liver disease (Child-Pugh classification C);kidney disease ; lack of patient cooperation;mental illness (major Depression, mania, psychosis); Hypotension;Hypertension; drug addiction.
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-chancellor of research of Babol University of Medical Sciences
Street address
Gangafrooz St, Babol University of Medical Sciences
City
Babol
Postal code
4717641367
Approval date
2013-11-09, 1392/08/18
Ethics committee reference number
30/3326/ژ/پ

Health conditions studied

1

Description of health condition studied
Acute Pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Pain
Timepoint
12 hours after colonoscopy
Method of measurement
Visoal analoge Scale

Secondary outcomes

1

Description
Sedation
Timepoint
12 hours after clonoscopy
Method of measurement
Ramsay Sedation Scale

2

Description
Nause and vomiting
Timepoint
12 hours after clonoscopy
Method of measurement
yes/no

Intervention groups

1

Description
The intervention group receives 1gr intravenous Paracetamol in 100 cc normal saline for 30 min before colonoscopy
Category
Treatment - Drugs

2

Description
Control group receives fentanyl and 100 ml DW5%30 minutes before colonoscopy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Rohani Teaching Hospital
Full name of responsible person
Abbasali Ahmady MD.
Street address
Rohani Teaching Hospital, Gangafrooz St.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of research of Babol University of Medical Sciences
Full name of responsible person
Mostafazadeh, Amrolah
Street address
Babol University of Medical Sciences,Gangafrooz St.
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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
Vice-chancellor of research of Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty

Data Dictionary *empty*