

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 receives Midazolam and Paracetamol (1gr in 100 cc of DW5%) for 30 min before colonoscopy and the control group receives 100 mL of saline and midazolam and fentanyl. Dose and time of prescription drugs includes midazolam 0.5 mg/ kg (maximum 2.5 mg) and fentanyl 0.5 to 1 mg / kg three minutes before colonoscopy. To both groups, if the rescue dose is needed, propofol 0.5 mg / kg as a bolus will be administered. 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 peripheral oxygen 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 (Aldrete 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)

###### Phone

+98 11 1223 8296

###### Email address

pamrimaleh@mubabol.ac.ir

##### 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  $\leq$  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/پ/ز

**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**

Visual analogue Scale

**Secondary outcomes****1****Description**

Sedation

**Timepoint**

12 hours after colonoscopy

**Method of measurement**

Ramsay Sedation Scale

**2****Description**

Nausea and vomiting

**Timepoint**

12 hours after colonoscopy

**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**  
Babol

## 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.  
**City**  
Babol  
**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  
**Full name of responsible person**  
Amrimaleh, Parviz  
**Position**  
Anesthesiologist, Flowship of critical care medicine  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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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*

