

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The comparison assessment the sedative effect of propofol-ketamin and propofol-fentanyl in colonoscopy

#### Protocol summary

##### Study aim

The comparison assessment the sedative effect of propofol-ketamine and propofol-fentanyl in colonoscopy

##### Design

A randomized clinical trial with parallel groups. 200 patients have randomly divided into intervention groups A and B with a table of random numbers and Randomizer software.

##### Settings and conduct

The population of this study was aged 18-55 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two Intervention groups with a table of random numbers by computer Group A: Fentanyl 0.7 microgram/kg and bolus dose of propofol 1 mg/kg Group B: propofol 1 mg/kg intravenously and bolus dose of Ketamine 0.5 mg/kg.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients scheduled for complete elective colonoscopy, 18-55 years old, ASA I-II Exclusion criteria: History of large bowel surgery, pregnancy, patients with psychiatric and emotional disorder, history of addiction, ;history of allergic reaction, history of pulmonary and metabolic disorders

##### Intervention groups

Group A: Fentanyl 0.7 microgram/kg and bolus dose of propofol 1 mg/kg Group B: propofol 1 mg/kg intravenously and bolus dose of Ketamine 0.5 mg/kg

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190529043750N1**

Registration date: **2019-06-18, 1398/03/28**

Registration timing: **retrospective**

Last update: **2019-06-18, 1398/03/28**

Update count: **0**

##### Registration date

2019-06-18, 1398/03/28

##### Registrant information

###### Name

mohammad esmaeili

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3233 8305

###### Email address

dresmaeili48@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-06, 1396/12/15

##### Expected recruitment end date

2019-03-06, 1397/12/15

##### Actual recruitment start date

2018-03-06, 1396/12/15

##### Actual recruitment end date

2019-03-06, 1397/12/15

##### Trial completion date

2019-03-06, 1397/12/15

##### Scientific title

The comparison assessment the sedative effect of propofol-ketamin and propofol-fentanyl in colonoscopy

##### Public title

Effect of propofol-ketamin and propofol-fentanyl in colonoscopy

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

patients scheduled for complete elective colonoscopy  
18-55 years old ASA class I-II

**Exclusion criteria:**

History of large bowel surgery  
Pregnancy  
Patients with psychiatric and emotional disorder  
History of addiction  
History of allergic reaction  
History of pulmonary and metabolic disorders

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **200**

Actual sample size reached: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the patients into two intervention groups  
Patients are randomly divided into two groups A and B with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not 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**

47176-41367

**Approval date**

2018-03-03, 1396/12/12

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1396.242

**Health conditions studied**

1

**Description of health condition studied**

disease of intestine,unspecified

**ICD-10 code**

k63.9

**ICD-10 code description**

disease of intestine,unspecified

**Primary outcomes**

1

**Description**

Pain

**Timepoint**

Before of discharge

**Method of measurement**

Visual Analogues Scale

**Secondary outcomes**

1

**Description**

Drug adverse effects

**Timepoint**

Before and after colonoscopy

**Method of measurement**

Before and after colonoscopy

2

**Description**

Colonoscopist satisfaction

**Timepoint**

After colonoscopy

**Method of measurement**

Numerical rating scale for colonoscopist satisfaction

3

**Description**

Blood pressure

**Timepoint**

Every 5 minutes

**Method of measurement**

Noninvasive cuff measurement

4

**Description**

Heart rate

**Timepoint**

Every 5 minutes

**Method of measurement**

Pulse counting

## Intervention groups

### 1

#### Description

Group A: Fentanyl 0.7 microgram/kg and bolus dose of propofol 1 mg/kg

#### Category

Treatment - Drugs

### 2

#### Description

Group B: propofol 1 mg/kg intravenously and bolus dose of Ketamine 0.5 mg/kg

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Rouhani Hospital

##### Full name of responsible person

Mohammad Esmaeili

##### Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-41367

##### Phone

+98 11 3233 8301

##### Email

dresmaeili48@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr Reza Ghadimi

##### Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-41367

##### Phone

+98 11 3219 7667

##### Email

rezaghadimi@yahoo.com

#### 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

Dr Mohammad Esmaeili

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

47176-41367

##### Phone

+98 113238301

##### Email

dresmaeili48@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Esmaeili

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Ayatollah Rouhani Hospital, Daneshgah Square,  
Ganjafrooz Avenue

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-41367

**Phone**

+98 113238301

**Email**

dresmaeili48@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Esmaeili

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ayatollah Rouhani Hospital, Daneshgah Square,  
Ganjafrooz Avenue

**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-41367

**Phone**

+98 113238301

**Email**

dresmaeili48@yahoo.com

## 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