

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of Etomidate-Fentanyl and Propofol -Fentanyl sedation in patients scheduled for colonoscopy

#### Protocol summary

##### Summary

80 patients scheduled for complete colonoscopy participated in the study.all patients recived fentanil 1 microgram/kg intravenously.they randomized into two groups .in the etomidate group (n=40),a bolus dose of etomidate 0.1 mg/kg was given ,followed by a continuous infusion at 5 microgram/kg/min .in the propofol group (n=50) a bolus dose of propofol 0.5 mg/kg was given, followed by continuous infusion at 25 microgram/kg/min.Vital signs,pain and sedation scores were recorded at the begining of colonoscopy and then every 5 min throughout the procedure.The quality of analgesia was assessed before hospital discharge and 24 h after the procedure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212195381N4**

Registration date: **2013-01-07, 1391/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-01-07, 1391/10/18

##### Registrant information

###### Name

Nadia Banihashem

###### Name of organization / entity

Babol University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 22 38296

###### Email address

nbanihashem@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor of Research Babol University of Medical Sciences

##### Expected recruitment start date

2012-07-30, 1391/05/09

##### Expected recruitment end date

2012-11-25, 1391/09/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Etomidate-Fentanyl and Propofol - Fentanyl sedation in patients scheduled for colonoscopy

##### Public title

Comparison of Etomidate-Fentanyl and Propofol - Fentanyl sedation in patients scheduled for colonoscopy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria:patients scheduled for comlete elective colonoscopy;ages of 18-55 years;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.

##### Age

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

##### Gender

Male

##### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 80

## 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

Babol University of Medical Sciences

##### Street address

Daneshgah Sq - Ganjafrooz Ave

##### City

Babol

##### Postal code

##### Approval date

2012-07-30, 1391/05/09

##### Ethics committee reference number

6830/30/ز/پ

## Health conditions studied

### 1

#### Description of health condition studied

Patients with intestine diseases who need colonoscopy

#### 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 measurrment

### 4

#### Description

Heart rate

#### Timepoint

Every 5 minutes

#### Method of measurement

Pulse counting

## Intervention groups

### 1

#### Description

Fentanil 1microgram/kg and bolus dose of propofol 0.5 mg/kg was given, followed by continuous infusion at 25microgram/kg/min.

#### Category

Treatment - Drugs

### 2

#### Description

Fentanil 1 microgram/kg intravenously and bolus dose of etomidate 0.1 mg/kg was given,followed by a continuous infusion at5microgram/kg/min

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Ruhani Hospital

**Full name of responsible person**

Dr Nadia Banihashem

**Street address****City**

Babol

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Nadia Banihashem

**Position**

Assistant Professor of Anesthesiology

**Other areas of specialty/work****Street address**Anesthesiology Department, Ruhani Hospital,  
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**Fax****Email**

nbanihashem@yahoo.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice-chancellor of Research Babol University Of  
Medical Sciences**Full name of responsible person**

Dr Amrolah Mostafazadeh

**Street address**Daneshgah Square, Ganjafrooz Avenue, Vice-  
chancellor Of Research**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 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**

Dr Nadia Banihashem

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Assistant Professor of Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Web page address****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*