

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 measurment

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

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+98 11 3233 8301

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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

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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

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Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Person responsible for scientific inquiries

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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