

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison of analgesic and sedative effect of combined propofol plus fentanyl and propofol plus ketamine in patients undergoing endoscopic retrograde of cholangiopancreatography

#### Protocol summary

##### Summary

The purpose of this study is comparison of analgesic and sedative effect of combined propofol plus fentanyl and propofol plus ketamine in patients undergoing endoscopic retrograde of cholangiopancreatography. In a clinical trial, 60 patients 18 to 80 years undergoing endoscopic retrograde of cholangiopancreatography were randomly divided into two equal groups. Addicted and severe heart failure patients are excluded. The Intervention group receives 1 mg midazolam and 0.5 mg/kg ketamine and the control group receives midazolam 1 mg and fentanyl 50 to 100 micrograms before endoscopic retrograde of cholangiopancreatography. In both groups 0.5 mg / kg propofol as a rescue bolus dose and then followed by 75microgram / kg / min infusion are administrated. Patients, anesthesiologist, endoscopist, and patients' examiner are unaware of the regimen. Depth of sedation (based on Ramsay scale), blood pressure, heart rate, and oxygen saturation of peripheral blood are recorded since starting medication every 2 minutes to 10 minutes and then every 5 minutes to end of procedure are recorded. Time of awakening based on Aldret score (equal to or greater than 9) and pain intensity based on Visual Analogue are recorded. Endoscopist and patient satisfaction after procedure are investigated based on the Likert scale.

#### General information

##### Acronym

ERCP: endoscopic retrograde of cholangiopancreatography

##### IRCT registration information

IRCT registration number: **IRCT201410187752N6**  
Registration date: **2014-12-09, 1393/09/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-09, 1393/09/18

##### 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

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for research of Babol University of Medical Sciences

##### Expected recruitment start date

2014-03-20, 1392/12/29

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of analgesic and sedative effect of combined propofol plus fentanyl and propofol plus ketamine in patients undergoing endoscopic retrograde of cholangiopancreatography

## Public title

Comparison of analgesic and sedative effect of combined propofol plus fentanyl and propofol plus ketamine

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age 18-80 years; ASA class  $\leq$  3

Exclusion criteria: age <18 years or > 80 years; Heart disease (arrhythmias, Aortic Stenosis, Ischemic Heart Disease, Heart failure) ; liver disease (Child-Pugh classification C); drug addiction.

## Age

From **18 years** old to **80 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

Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

##### City

Babol

##### Postal code

471764136

#### Approval date

2014-10-12, 1393/07/20

#### Ethics committee reference number

4709

## Health conditions studied

### 1

#### Description of health condition studied

Sedation

#### ICD-10 code

y48.2

#### ICD-10 code description

Other and unspecified general anaesthetics

## Primary outcomes

### 1

#### Description

Sedation

#### Timepoint

Every 2 minutes till 10 minutes and then every 5 minutes till 1 hour

#### Method of measurement

Ramsay Sedation Scale

### 2

#### Description

Pain

#### Timepoint

Every 2 minutes till 10 minutes and then every 5 minutes till 1 hour

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Every 2 minutes till 10 minutes and then every 5 minutes till 1 hour

#### Method of measurement

sphygmomanometer

### 2

#### Description

Respiratory Rate

#### Timepoint

Every 2 minutes till 10 minutes and then every 5 minutes till 1 hour

#### Method of measurement

observation

## Intervention groups

### 1

#### Description

The Intervention group receives 1 mg midazolam and 0.5 mg/kg ketamine before ERCP and 0.5 mg / kg propofol as a rescue bolus dose then followed by 75 microgram / kg / min infusion

**Category**

Treatment - Drugs

**2****Description**

the control group receives midazolam 1 mg and fentanyl 50 to 100 micrograms before ERCP and 0.5 mg / kg propofol as a rescue bolus dose and then followed by 75microgram / kg / min infusion

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rohany teaching Hospital

**Full name of responsible person**

Amri Mleh Parviz

**Street address**

Rohany teaching Hospital, Ganjafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

**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**

Ali Moghadamnia

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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**

Vice-chancellor of research of Babol University of Medical Sciences

**Full name of responsible person**

Amri Maleh Parviz

**Position**

Associated professor

**Other areas of specialty/work****Street address**

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**Position**

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**Position**

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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*