

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

pamrimaleh@mubabol.ac.ir

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

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

Ali Moghadamnia

Street address

Babol University of Medical Sciences, Gangafrooz St, Daneshgah Square, Babol, Iran

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**

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**

Rohany Hospital, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

City

Babol

Postal code

4717641376

Phone

+98 11 1223 8296

Fax

+98 11 1223 8296

Email

pamrimaleh@yahoo.com

Web page address**Person responsible for scientific 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

Anesthesiologist

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

Rohany Hospital, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran Babol

City

Babol

Postal code**Phone**

+98 11 1223 8296

Fax**Email**

pamrimaleh@yahoo.com

Web page address**Person responsible for updating data****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/Anesthesiologist

Other areas of specialty/work

Street address

Rohny Hospital, Ganjafrooz Street, Daneshgah
Square, Babol, Mazandaran, Iran

City

Babol

Postal code

4717641376

Phone

00

Fax**Email**

pamrimaleh@yahoo.com

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