Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison effect of Propofol-Fentanyl with Propofol-Ketamine for sedation in patients undergoing ERCP

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done to Comparison effect of Propofol-Fentanyl with Propofol-Ketamine for sedation in patients undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP). Inclusion criteria: admitted patients for diagnostic and therapeutic ERCP in Imam Khomeini hospital; 18 to 65 years old; anesthesia risk of 1, 2 (According to American society of anesthesiologist's classification). Exclusion criteria: patient refuse; under 18 and over 65 years old; a history of drug abuse; sensitivity to egg; contraindication of Fentanyl or Ketamine. Patients will be randomly allocated into two groups according to table of random numbers. Groups "one" and "two" will receive intravenous Propofol 0.5 mg/kg with intravenous Fentanyl 1 µg/kg and intravenous Propofol 0.5 mg/kg with intravenous Ketamine 0.5 mg/kg, respectively. Sedation score of patient in 4 different times, during procedure, according to Ramsay sedation score is measured. Postoperative pain and nausea and vomiting will measured at 1 hour after procedure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031316976N1**
Registration date: **2014-04-15, 1393/01/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-15, 1393/01/26

Registrant information

Name
Sanaz Noorizade
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2014-06-15, 1393/03/25

Expected recruitment end date

2014-12-15, 1393/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Propofol-Fentanyl with Propofol-Ketamine for sedation in patients undergoing ERCP

Public title

Comparison effect of Propofol-Fentanyl with Propofol-Ketamine for sedation in patients undergoing ERCP

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: admitted patients for diagnostic and therapeutic ERCP in Imam Khomeini hospital; 18 to 65 years old; anesthesia risk of 1, 2 (According to American

society of anesthesiologist's classification). Exclusion criteria: patient refuse; under 18 and over 65 years old; a history of drug abuse; sensitivity to egg; contraindication of Fentanyl or Ketamine.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Ahvaz Jundishapur University of Medical Sciences

Street address
No.12, Chamber Sadaf, Golestan Blvd

City
Ahvaz

Postal code
6135733777

Approval date
2013-11-16, 1392/08/25

Ethics committee reference number
ajums.REC.1392.286

Health conditions studied

1

Description of health condition studied
(Endoscopic Retrograde Cholangio Pancreatography)ERCP

ICD-10 code
51.10

ICD-10 code description
Fluoroscopy of Biliary and Pancreatic Ducts using Low Osmolar Contrast

Primary outcomes

1

Description
Sedation Score

Timepoint
Four times, during procedure

Method of measurement
Ramsay Sedation Score

Secondary outcomes

1

Description
Pain

Timepoint
One hour after procedure

Method of measurement
Visual Analogue Scale

2

Description
Nausea

Timepoint
One hour after procedure

Method of measurement
Zero for not having nausea, One for mild nausea, Two for moderate nausea and Three for sever nausea

3

Description
Vomiting

Timepoint
One hour after procedure

Method of measurement
Zero for the patients not experiencing vomiting, 1 for the little vomiting, 2 for vomiting gastric contents and 3 for vomiting food particles.

Intervention groups

1

Description
Drugs: 1-Propofol: Dose: 0.5mg/kg Number of using: Once Factory name: Astra Zeneca Country's Name:India Location prescribed: Intravascular Administration time: At the beginning of the procedure 2-Ketamine: Dose: 0.5mg/kg Number of using: Once Factory name: Rotexmedica Manufacturing Country's Name: Germany Location prescribed: Intravascular Administration time: At the beginning of the procedure

Category
Treatment - Drugs

2

Description

Drugs: 1-Propofol: Dose: 0.5mg/kg Number of using: Once Factory name: Astra Zeneca Country's Name:India Location prescribed: Intravascular Administration time: At the beginning of the procedure 2-Fentanyl Dose: 1mcg/kg Number of using: Once Factory name: Chekad Manufacturing Country's name: Iran Location prescribed: Intravascular Administration time: At the beginning of the procedure

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Educational Hospital

Full name of responsible person
Dr. Reza Akhundzadeh

Street address
No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Dr. Mostafa Feghhi

Street address
No. 21, Ave. 1, Golestan Blvd.

City
Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Ahvaz Jundishapur 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
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Sanaz Noorizade

Position
Resident of Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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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