Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Assessment of the effects of ketamine-fentanyl combination versus propofol- remifentanil combination for sedation during Endoscopic retrograde cholangiopancreatography

Protocol summary

Summary
Chief Aim: Comparing the effects of ketamine- fentanyl combination and propofol-remifentanil combination for sedation during Endoscopic retrograde cholangiopancreatography. Study Design: Interventional – randomized – double blinded Target Population: patients who will undergo ERCP in St. Alzahra hospital, Isfahan, Iran and consented to participate in this study Key Inclusion criteria: Patient at age between 25 to 70 years, ASA physical status I and II, Key Exclusion criteria: Occurring severe ERCP complications such as perforation and bleeding, ERCP procedural failure Sample Size: 62 (31 per group) Intervention: The patients will be randomly allocated into two groups. Group 1 will receive Ketamine – Fentanyl combination and group 2 will receive Propofol – Remifentanil combination. Date of intervention: 2011.08.22 to 2014.03.20 Primary Outcome: sedation level

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2014052317651N1**
Registration date: **2014-06-12, 1393/03/22**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2014-06-12, 1393/03/22

Registrant information
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Recruitment status
Recruitment complete
Funding source
Isfahan University of medical sciences

Expected recruitment start date
2012-08-22, 1391/06/01
Expected recruitment end date
2014-03-20, 1392/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effects of ketamine-fentanyl combination versus propofol- remifentanil combination for sedation during Endoscopic retrograde cholangiopancreatography

Public title
effects of ketamine-fentanyl combination and propofol-remifentanil combination for sedation during Endoscopic retrograde cholangiopancreatography
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: Patient at age between 25 to 70 years; ASA physical status I and II; Patients without anatomic airway abnormalities; Patients without severe

cardiovascular and respiratory disease; Patients without severe psychological problem; Patients who are not pregnant; Patients who are not smoker or addict; Patients without history of previous ERCP. Exclusion criteria: Occurring severe ERCP complications such as perforation and bleeding; ERCP procedural failure; Changing the sedation plan to the general anesthesia.

Age
From **25 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

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
Isfahan university of medical sciences, faculty of medicine

Street address
Isfahan university of medical sciences, faculty of medicine Hezarjerib Ave, Azadi square

City
Isfahan

Postal code
81746

Approval date
2011-11-09, 1390/08/18

Ethics committee reference number
390425

Health conditions studied

1

Description of health condition studied
Disorders of gallbladder, biliary tract and pancreas

ICD-10 code
K87

ICD-10 code description
Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere

Primary outcomes

1

Description
Sedation level

Timepoint
every 5 min during the first 15 min of the procedure and then every 15 min until the end of procedure

Method of measurement
Ramsay scale

Secondary outcomes

1

Description
Dose repeats

Timepoint
during ERCP

Method of measurement
Questionnaire

2

Description
Recovery time

Timepoint
after procedure

Method of measurement
Aldrete score

3

Description
Systolic blood pressure

Timepoint
before the intervention then every 5 min during the first 15 min of the procedure and then every 15 min until the end of procedure and then at the entrance to the recovery room and after first 15 min

Method of measurement
sphygmomanomete

4

Description
Heart rate

Timepoint
before the intervention then every 5 min during the first 15 min of the procedure and then every 15 min until the end of procedure and then at the entrance to the recovery room and after first 15 min

Method of measurement
Beat/minute

5

Description
O2 saturation
Timepoint
before the intervention then every 5 min during the first 15 min of the procedure and then every 15 min until the end of procedure and then at the entrance to the recovery room and after first 15 min
Method of measurement
Pulse oximetry

6

Description
Respiratory rate
Timepoint
before the intervention then every 5 min during the first 15 min of the procedure and then every 15 min until the end of procedure and then at the entrance to the recovery room and after first 15 min
Method of measurement
per minute

7

Description
Retching
Timepoint
during ERCP
Method of measurement
Questionnaire

8

Description
Apnea occurrence
Timepoint
during ERCP
Method of measurement
Questionnaire

9

Description
Patient’s pain intensity
Timepoint
at 60 min post procedure
Method of measurement
Visual analogue scale(VAS)

10

Description
Patient’s satisfaction
Timepoint
after procedure
Method of measurement
Visual analogue scale(VAS)

11

Description
Intensity of nausea
Timepoint
at 60 min post procedure
Method of measurement
Visual analogue scale(VAS)

12

Description
Endoscopist’s satisfaction
Timepoint
after procedure
Method of measurement
Visual analogue scale(VAS)

Intervention groups

1

Description
Ketamine group will receive a loading dose of Ketamine 0.5 mg/Kg body weight intravenously over 60 seconds and then Fentanyl 1 mcg/Kg body weight intravenously. According to sedation level, in Ramsay sedation score(RSS) 1 and RSS2, the initial sedation will be inadequate and the repeated dose will be necessary to accomplish the procedure and additional incremental dose of Ketamine 0.2 mg/Kg body weight will be given intravenously to patient in Ketmine group.
Category
Treatment - Drugs

2

Description
Propofol group will receive Propofol l mg/Kg body weight intravenously over 60 seconds and then Remifentanil 0.05 mcg/Kg body weight/min intravenously. Intravenous infusion of propofol will be maintained by 50 mcg/Kg body weight/min throughout ERCP. In RSS1 and RSS2 the initial sedation will be inadequate and the repeated dose will be necessary to accomplish the procedure and intravenous infusion of propofol will be increased up to 100 µg/Kg body weight/min to patient in Propofol group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Sayed Morteza Heidari - Anaesthesiologist
Street address
Sofe Ave, Alzahra Hospital
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan university of medical sciences, faculty of medicine
Full name of responsible person
Dr. Bahram NasrEsfahani/ financial deputy
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Isfahan university of medical sciences, faculty of medicine Hezarjerib Ave, Azadi square
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan university of medical sciences, faculty of medicine
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
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Person responsible for updating data

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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