Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

A comparative study of the sedative and analgesic effects of two combinations of dexmethomidine-ketamine (Ketodex) and propofol-fentanyl (Fenofel) in patients undergoing endoscopic retrograde cholangiopancreatography.

Protocol summary

Study aim
Determine the the sedative effects of and analgesic effects of two combinations of dexmedetomidine-ketamine (Ketodex) to propofol- fentanyl (Fenofol) in patients undergoing Endoscopic Retrograde Cholangiopancreatography

Design
Clinical trial,with parallel groups,three blinded, randomized,phase 3 on 120 patients,random allocation software was used for randomization

Settings and conduct
This study is a three-blind randomized clinical trial and the community study of patients who are candidates for endoscopic retrograde cholangiopancreatography in the year 2023 are hospitalized.Patients who met all the inclusion criteria after obtaining informed consent,they entered the study.this Patients are randomly divided into 2 groups.

Participants/Inclusion and exclusion criteria
Study inclusion criteria:Age above 18 years,Consent to enter the study,Patients who are candidates for endoscopic retrograde cholangiopancreatography,Patients with American Society of Anesthesiologists (ASA) I,II Criteria for not entering the study:Patients with high blood pressure,coronary heart disease and central nervous system disorders,Patients with known allergies to study drugs,pregnancy,Airway's disease

Intervention groups
The Fenofol group received 1 µg/kg fentanyl and 1 mg/kg propofol over 30 seconds,followed by propofol at 2 to 4 mg/kg/h. The Ketodex group received 0/5 µg/kg dexmedetomidine and 1 mg /kg of ketamine as a loading dose infusion over 2 to 5 minutes and received dexmedetomidine at 0.5 µg/kg/h and ketamine at 1 to 2 mg/kg/h

Main outcome variables
Amount of pain,quality of relaxation,age,sex,oxygen saturation level,diastolic blood pressure,systolic blood pressure,heart rate,duration of ERCP, length of stay in recovery,additional medication for sedation,ASA,underlying disease,disease Background leading to ERCP,duration of anesthesia,patient satisfaction,gastroenterologist satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N55**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**
Update count: **0**

Registration date
2023-12-14, 1402/09/23

Registrant information

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Behzad Nazemroaya
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Isfahan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01
Expected recruitment end date
2024-03-18, 1402/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the sedative and analgesic effects of two combinations of dexmethomidine-ketamine (Ketodex) and propofol-fentanyl (Fenofel) in patients undergoing endoscopic retrograde cholangiopancreatography.

Public title
Comparison of sedative and analgesic effects of two combinations of dexmethomidine-ketamine (Ketodex) and propofol-fentanyl (Fenofol)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Consent to enter the study Patients who are candidates for endoscopic retrograde cholangiopancreatography Patients with American Society of Anesthesiologists (ASA) I,II
Exclusion criteria:
Patients with high blood pressure, coronary heart disease and central nervous system disorders Patients with known allergies to study drugs pregnancy Airway's disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way. The samples are randomly placed in three intervention groups 1, 2 by means of random allocation software. Sampling continues until the samples in all two groups reach the set limit
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is a triple blind clinical trial, before obtaining the consent to participate in the study from the patients, in addition to explaining to them that they are randomly participating in two drug groups and they will get information about the type of drugs, but in what They will not be informed if they are placed in a group, an anesthesiologist, as the person responsible for collecting data and evaluating the outcome, is not aware of the groups, nor is the statistician, who plays the role of an analyst, aware of the groups, and after receiving the results by the presenter Decoding takes place, so we can do the study in a triple blind way.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-08-08, 1402/05/17
Ethics committee reference number
IR.MUI.MED.REC.1402.175

Health conditions studied

1

Description of health condition studied
Analgesia and sedation in patients undergoing endoscopic retrograde cholangiopancreatography
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation rate of patients
Timepoint
The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes

and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

The level of patients sedation will be evaluated using the Modified Aldrete score,whose validity and reliability have been confirmed by a recent stud

2

Description

Analgesia of patients

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

Painlessness of patients will be evaluated using the Visual Analogue Scale (VAS) whose validity and reliability have been confirmed by a recent study.

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

Barometer

2

Description

Diastolic blood pressure

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

Barometer

3

Description

Pulse rate

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

ECG

4

Description

Respiratory rate

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

Breaths per minute stopwatch

5

Description

Oxygen saturation

Timepoint

The base time (before the start of the intervention) and then every 15 minutes in the operating room and in the first hour of recovery every 15 minutes to 45 minutes and then in the 2nd and 4th hours after ERCP were recorded.

Method of measurement

Pulse oximeter

Intervention groups

1

Description

The first intervention group: received 1 µg/kg of fentanyl and 1 mg/kg of propofol in 30 seconds and then propofol injection at 2 to 4 mg/kg per hour. The second intervention group: 0.5 µg/kg of dexmedetomidine and 1 mg/kg of ketamine in 2 divided boluses of each drug, alternately in 30 seconds, and 0.5 µg/kg per hour of dexmedetomidine and ketamine with 1 to 2 will receive mg/kg per hour.

Category

Treatment - Drugs

2

Description

Intervention group: 2nd: Half microgram/kg of dexmedetomidine and 1 mg/kg of ketamine were given as a loading dose over 2 to 5 minutes as infusion, and 0.5 microgram/kg per hour of dexmedetomidine and ketamine with 1 to 2 mg/ kg per hour .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahara hospital

Full name of responsible person

Mohammad Reza Safavi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Sorour sadat Asayesh
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Medical student/ Intern
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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