Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of hemodynamic and respiratory effects of premedication with fentanyl or fentanyl and midazolam during anesthesia for endoscopic retrograde cholangiopancreatography

Protocol summary

Summary

Despite all methods used for the anesthesia of the patients undergoing ERCP, complete immobility required for an accurate procedure would not happen unless hypnotic agents such as propofol are used. On the other hand, administration of propofol in combination with other medications such as opioids or benzodiazepines could be associated with increased risk of apnea and hemodynamic instability, especially in the elderly or those with accompanying diseases. In this randomized, double blinded and single center study, the primary outcome was comparing the hemodynamic and respiratory effects of premedication with fentanyl (control) or fentanyl and midazolam (intervention) during anesthesia for endoscopic retrograde cholangiopancreatograph. Inclusion criteria are the patients with ASA class I-III who will undergo endoscopic retrograde cholangiopancreatography(ERCP). Exclusion criteria from the study are: Emergency ERCP, Liver or kidney diseases, previous history of sedatives or tranquilizers. The respiratory impacts including the emergence of the apnea before and after the intervention will be compared between two groups. The selected premedicatoin combination from the study would provide more appropriate and safer anesthesia for the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031120795N2**
Registration date: **2016-04-29, 1395/02/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-29, 1395/02/10

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic and respiratory effects of premedication with fentanyl or fentanyl and midazolam during anesthesia for endoscopic retrograde cholangiopancreatography

Public title

Premedication with fentanyl or fentanyl and midazolam for endoscopic retrograde cholangiopancreatography

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients with ASA class I-III who will undergo endoscopic retrograde cholangiopancreatography(ERCP). Exclusion criteria: Emergency ERCP; Liver or kidney diseases; previous history of sedatives or tranquilizers.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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 Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences
City
Tabriz
Postal code
Approval date
2015-11-09, 1394/08/18
Ethics committee reference number
TBZMED.REC.94.713

Health conditions studied

1

Description of health condition studied
Cholelithiasis
ICD-10 code
K80
ICD-10 code description
Any condition listed in K80.2 with acute cholecystitis

Primary outcomes

1

Description
respiratory effects
Timepoint
Before and instantly after intervention
Method of measurement
Apnea presence

Secondary outcomes

1

Description
Hemodynamic effects
Timepoint
After intervention
Method of measurement
Blood pressure and Heart rate measuring

Intervention groups

1

Description
Intervention group premedication with fentanyl 1 microgram/kg before anesthesia induction
Category
Treatment - Drugs

2

Description
Control group premedication with fentanyl 1 microgram/kg and midazolam 0.02 mg/kg before anesthesia induction
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Samad Eslam Jamal Golzari
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Imam Reza Hospital, Golgasht St., Tabriz
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Sponsors / Funding sources

1

Sponsor
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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
Tabriz 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

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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