

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Samad Golzari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Street address

Imam Reza Hospital, Golgasht St., Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Street address

Imam Reza Hospital, Golgasht St., Tabriz

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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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Assistant Professor

Other areas of specialty/work

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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