

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of propofol infusion with and without lidocaine on pain and need for sedation during Endoscopic Retrograde Cholangio Pancreatography(ERCP)

Protocol summary

Study aim

Effects of propofol infusion with and without lidocaine on pain and need for sedation during Endoscopic Retrograde Cholangio Pancreatography(ERCP)

Design

This study will be conducted as a randomized clinical trial (blocks of four), double-blind, with parallel groups, without a control group, and phase 2-3, with the participation of 80 patients.

Settings and conduct

This study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups, without a control group and phase 2-3 and with the participation of 80 ERCP candidates referred to Imam Reza Hospital (Tabriz) will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: class I to III patients according to ASA and candidates for ERCP, and exclusion criteria include: patients with arterial oxygen saturation less than 90%, heart rate less than 50, and convulsive patients.

Intervention groups

For patients in the intervention group, they will receive 1.5 milligrams of lidocaine per kilogram of weight, and then they will receive 4 milligrams of lidocaine per kilogram of weight in one hour as an infusion, and for patients in the control group, the same amount will be given. Normal saline will be infused. Then propofol will be given as a propofol infusion at a rate of 2 to 4 mg per kilogram of weight per hour.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N33**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-07, 1402/02/17

Expected recruitment end date

2024-05-06, 1403/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of propofol infusion with and without lidocaine on pain and need for sedation during Endoscopic Retrograde

Public title

Effects of propofol infusion with and without lidocaine on pain and need for sedation during ERCP

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class I to III patients ERCP candidate

Exclusion criteria:

Patients with arterial oxygen saturation less than 90%

Heart rate less than 50 Seizure patients

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they were divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The thesis results analyst who analyzed the expected outcome and also the participants remained unaware of the type of procedure performed and were blind during the study; Therefore, this study was conducted in a double-blind manner.

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

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2023-05-07, 1402/02/17

Ethics committee reference number

IR.TBZMED.REC.1402.101

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

Once every 10 minutes and for thirty minutes

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Sedation

Timepoint

For a moment and for thirty minutes

Method of measurement

Patient observation

Intervention groups

1

Description

Intervention group: For the patients of this group, 1.5 mg of lidocaine will be injected for each kilogram of weight,

and then they will receive 4 mg of lidocaine per kilogram of weight in one hour as an infusion. Then propofol as an infusion. It will be given at a rate of 2 to 4 mg per kilogram of weight per hour. Then, during ERCP, the intensity of pain and the level of sedation will be checked.

Category

Treatment - Drugs

2

Description

Control group: For the patients of this group, 4 cc of normal saline will be infused at the beginning and then 2 to 4 cc per hour. Then propofol will be given as an infusion at a rate of 2 to 4 mg per kilogram of weight per hour. became. Then, during ERCP, the intensity of pain and the level of sedation will be checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Marjan Dehdilani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Full name of responsible person

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Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Latest degree

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