

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

Cholangio Pancreatography(ERCP)

### 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

**Street address**

Imam Reza Hospital, Azadi Ave

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East Azarbaijan

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6165665631

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+98 41 3335 5921

**Email**

mkhanbabayi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

**Street address**

Imam Reza Hospital, Azadi Ave

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**Email**

Ajouyban@hotmail.com

**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

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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**

Mehdi Khanbabayi Gol

**Position**

MSc in Nursing Education

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**City**

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**Province**