

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the effects of dexmedetomidine and ketamine on Oddi sphincter tone during ERCP

#### Protocol summary

##### Study aim

Comparison of the effects of dexmedetomidine and ketamine on sphincter tone during endoscopic retrograde cholangiopancreatography (ERCP)

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 84 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

After connecting the monitoring, the patients are hydrated with normal saline serum, and with 0.3 mg/kg of midazolam and 2 micrograms of fentanyl, propofol infusion of 50 to 70 per hour and divided into three groups, the first group of which is ketamine with a dose of 0.5 µg/kg, the second group will be injected with 0.5 µg/kg of dexmedetomidine and the third group will be injected with Plaspo drug. Oddi's sphincter tone is measured by the doctor performing the ERCP. For patients in both groups, basic vital signs, including mean arterial blood pressure, heart rate, and blood oxygen saturation percentage, are measured and recorded in the information form. After taking the patient's history and his complete examination and recording the results in the file, a vein is taken from the cubital area. Hemodynamic changes (MAP, HR, Sat o<sub>2</sub>) are measured and compared at 5, 10, 20 and 30 minutes after drug injection.

##### Participants/Inclusion and exclusion criteria

Entry criteria: ERCP candidate patients who need anesthesia,

##### Intervention groups

The first group is ketamine with a dose of 0.5 µg/kg, the second group is 0.5 µg/kg of dexmedetomidine, and the third group is Plaspo drug.

##### Main outcome variables

Oddi sphincter tone and hemodynamic changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230817059177N1**

Registration date: **2023-10-21, 1402/07/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

##### Registration date

2023-10-21, 1402/07/29

##### Registrant information

##### Name

Mahrokh Vardipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 933 350 7138

##### Email address

mahrokh.vardipour@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-22, 1402/06/31

##### Expected recruitment end date

2023-12-20, 1402/09/29

##### Actual recruitment start date

2023-09-22, 1402/06/31

##### Actual recruitment end date

2023-12-20, 1402/09/29

##### Trial completion date

2024-01-19, 1402/10/29

##### Scientific title

Comparison of the effects of dexmedetomidine and ketamine on Oddi sphincter tone during ERCP

#### Public title

Comparison of the effects of dexmedetomidine and ketamine on Oddi sphincter tone during ERCP

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

ERCP candidate patients who need anesthesia, , in the age range of 18 to 65 years, not suffering from cardiovascular diseases, kidney or liver failure not addicted to drugs, convulsions, not having contraindications for the use of dexmedetomidine, ketamine, which are classified as class 1 and 2 of the association American Anesthesia (ASA) and II, I class are selected

##### Exclusion criteria:

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **84**

Actual sample size reached: **84**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients are randomly divided into three groups based on the case number, the patients are placed in separate groups based on the case number, the even and odd number on the right, simple cluster randomization, table of random numbers

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

In this study, both the patient and the therapist are blinded, including the participants and doctors who do not know which drug they have received

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

ethics committee of ahwaz university of medical sciences

#### Street address

Golestan highway , ahwaz university of medical science

#### City

ahwaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Approval date

2023-07-21, 1402/04/30

#### Ethics committee reference number

IR.AJUMS.REC.1402.251

### Health conditions studied

#### 1

##### Description of health condition studied

ERCP

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

The effect of dexmedetomidine on the tone of the sphincter of Audi based on the pain level

##### Timepoint

5-10-20-30 min of study

##### Method of measurement

questionnaire

#### 2

##### Description

The effect of ketamine drug on the sphincter of Audi, drug side effects

##### Timepoint

5-10-20-30 min of study

##### Method of measurement

questionnaire

### Secondary outcomes

#### 1

##### Description

level of relaxation

##### Timepoint

5-10-20-30 min of the study

##### Method of measurement

questionnaire

#### 2

##### Description

hypertention

##### Timepoint

5-10-15-20 min of the study

## Method of measurement

questionnaire

### 3

#### Description

heartrate

#### Timepoint

in the procedure of study

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group one : The intervention group of Rotax ketamine (C<sub>13</sub>H<sub>16</sub>CINO) with a dose of 0.5 mg per kilogram of weight for 40 seconds intravenously one to three times by Hakim Mehr Company

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group2 : The intervention group of two dexmedetomidine C<sub>13</sub>H<sub>16</sub>N<sub>2</sub> with a dose of 0.5 mg per kg 50 seconds intravenously one to three times Elixir company

#### Category

Treatment - Drugs

### 3

#### Description

Control group: placebo

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

golestan hospital

##### Full name of responsible person

مهشید وزیری

##### Street address

farvardin boulevard, golestan hospital

##### City

اهواز

##### Province

Khuzestan

##### Postal code

6441945781

##### Phone

+98 61 3337 4058

##### Email

mahrokh.vardipour@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

fatemeh javaherforoshzadeh

##### Street address

golestan highway , ahvaz university of medical science university

##### City

ahwaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3314 0000

##### Email

aduaum@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

mahshid vaziri

##### Position

associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

farvardin boulevard , golestan hospital

##### City

ahwaz

##### Province

Khuzestan

##### Postal code

6335715794

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

mahshid vaziri

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associate professor

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## Person responsible for updating data

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Ahvaz University of Medical Sciences

**Full name of responsible person**

mahshid vaziri

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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ahvaz

**Province**

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**Postal code**

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**Phone**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

only the data which is associated to result and outcome of study will be published and available for researcher for more research

**When the data will become available and for how long**

after the study is published, the data will be available

**To whom data/document is available**

researchers, academic and scientific institution

**Under which criteria data/document could be used**

in metanalysis and similar study

**From where data/document is obtainable**

refer to the vice president of research and technology. in addition of giving ethic code of the data will be available for researchers

**What processes are involved for a request to access data/document**

the researcher can access to the data after getting ethic code from ethic committee of research of jondishapour university by mailing to research and technology unit

**Comments**