

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 o₂) 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

Khuzestan

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 (C₁₃H₁₆CINO) 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 C₁₃H₁₆N₂ 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

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اهواز

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6441945781

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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

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ahwaz

Province

Khuzestan

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6135715794

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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

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City

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Person responsible for scientific inquiries

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Full name of responsible person

mahshid vaziri

Position

associate professor

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Person responsible for updating data

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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