

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

the Comparative study effect of Dexmedetomidine and Ketamine on post operative analgesia after laparoscopic cholecystectomy surgery

Protocol summary

Study aim

study effect of Dexmedetomidine and Ketamine on post operative analgesia after laparoscopic cholecystectomy surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 252 patients, randomization function of Excel software was used for randomization.

Settings and conduct

This study will be conducted as a double-blind clinical trial on (252) patients in 1402-1403 in Imam Hospital of Ahvaz-Iran after obtaining permission from the Ethics Committee of Jundishapur University of Ahvaz on patients who undergo laparoscopic cholecystectomy surgery. After visiting the operating room and initial examinations, the patients will have an intravenous line. Initial monitoring will include pulse oximetry, non-invasive sphygmomanometer, and electrocardiography. Initial hemodynamic parameters such as heart rate and blood pressure will be recorded upon arrival, immediately after receiving the study drugs, every 5 minutes to 15 minutes, and then every 15 minutes until the end of the procedure. In the following, the hemodynamic parameters and duration of analgesia (VAS score) in 24, 12, 6, 1 hours after surgery

Participants/Inclusion and exclusion criteria

inclusion criteria : patients with ASA class I and II, patient age between 18 and 50 years. Exclusion criteria : emergency surgery, sensitivity to drugs used in the study, abuse or alcohol, lack of consent to participate in the study, psychiatric disorders

Intervention groups

Patients are randomly divided into three groups (ketamine, dexmedetomidine and control). Group K: In this group, 0.5 mg/kg/h of ketamine is injected intravenously 15 minutes before surgical incision. Group D: In this group, 0.6 µg/kg/min dexmedetomidine is injected intravenously 15 minutes before surgical incision. Group C: In this group, normal saline is injected

intravenously.

Main outcome variables

Post operative pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191025045235N2**

Registration date: **2023-12-13, 1402/09/22**

Registration timing: **prospective**

Last update: **2023-12-13, 1402/09/22**

Update count: **0**

Registration date

2023-12-13, 1402/09/22

Registrant information

Name

Seyedeh fatemeh Hosseinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3443 5099

Email address

drhosseinejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
the Comparative study effect of Dexmedetomidine and Ketamine on post operative analgesia after laparoscopic cholecystectomy surgery

Public title
Comparative study effect of Dexmedetomidine and Ketamine on post operative analgesia after laparoscopic cholecystectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with ASA class I and II patients age between 18 and 50 years
Exclusion criteria:
emergency surgery sensitivity to the drugs used in the study abuse or alcohol lack of consent to participate in the study psychiatric disorder patients who, for some reason, changed their operation from laparoscopic during surgery. The surgery is open.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **252**

Randomization (investigator's opinion)
Randomized

Randomization description
People were divided into two groups completely randomly based on the random block permutation method. For example, for blocks of four, we imagined 6 blocks ABBA, AABB, ABAB, BABA, BBAA, BAAB, which should be n/4 We sampled from these blocks in the form of placement. The random sequence was obtained from the website www.sealedenvelope.com. Patients are entered in the order of entry. Patients are randomly divided into three groups (ketamine, dexmedetomidine and control). Group: K In this group, 0.5 mg/kg/h of ketamine (Panpharma, Germany) is injected intravenously 15 minutes before surgical incision. Group: D In this group, 0.6 µg/kg/min dexmedetomidine (Exir Company, Iran) is injected intravenously 15 minutes before surgical incision

Blinding (investigator's opinion)
Double blinded

Blinding description
the patient and the anesthesia technician are unaware of the type of injected drug. the medicine is already prepared and given to the technician

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Imam Khomeini Hospital, Azadegan Ave, Ahvaz
City
Ahvaz
Province
Khuzestan
Postal code
6135913441

Approval date
2023-08-12, 1402/05/21

Ethics committee reference number
IR.AJUMS.REC.1402.276

Health conditions studied

1

Description of health condition studied
cholelithiasis

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain

Timepoint
1-2-4-6 hours after the surgery

Method of measurement
After visiting the operating room and initial examinations, all patients will have an intravenous line with an 18 size angiocath. Initial monitoring will include pulse oximetry, non-invasive sphygmomanometer, and electrocardiography. Initial symptoms will be recorded and treated with midazolam 0.03 mg/kg, fentanyl 2 µg/kg, sodium thiopental 5 mg/kg and atracurium 0.5 mg/kg are placed under anesthesia induction and then intubated. They are connected to a ventilator and are anesthetized with isoflurane 1 ml during the operation and 0.1 mg/kg morphine is given to reduce pain during the operation. The patients are randomly divided into

three groups (ketamine, dexmedetomidine and control). Group K: 15 minutes before surgical incision, 0.5 mg/kg/h of ketamine (Panpharma, Germany) is injected intravenously. Group D: In this group, 15 minutes before surgical incision, 0.6 µg/kg/min of dexmedetomidine (Exir, Iran) is injected into It is injected intravenously. Group C: In this group, normal saline is injected intravenously. Primary hemodynamic parameters such as heart rate and blood pressure are recorded upon arrival, immediately after receiving the study drugs, every 5 minutes to 15 minutes, and every 15 minutes until the end of the procedure. Next, the hemodynamic parameters and duration of painlessness, VAS score will be recorded at 24, 12, 6, 1 hours after the operation. 0 no pain), up to (VAS=10, the worst type of pain after surgery). If the score is higher than 3 after the surgery, painkillers will be prepared and injected (morphine 2-3 mg).

Secondary outcomes

1

Description

Blood pressure and heart rate changes

Timepoint

Every 15 minutes during operation

Method of measurement

With pressure gauge and monitoring device

Intervention groups

1

Description

Intervention group: Patients are randomly divided into three groups (ketamine, dexmedetomidine and control). Group K: In this group, 0.5 mg/kg/h of ketamine (Panpharma, Germany) is injected intravenously 15 minutes before surgical incision. Group D: In this group, 0.6 µg/kg/min of dexmedetomidine (Exir Company, Iran) is injected intravenously 15 minutes before surgical incision. Group C: In this group, normal saline is injected intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Seyedeh Fatemeh Hosseini Nejad

Street address

Imam Khomeini Hospital, Azadegan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135913441

Phone

+98 916 615 2270

Email

drhosseininejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

dr. Nima Bakhtiari

Street address

Imam Khomeini Hospital, Azadegan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135913441

Phone

+98 916 615 2270

Email

drhosseininejad@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Ahvaz Jundishapur 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

Seyedeh Fatemeh Hosseininejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, Azadegan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135913441

Phone

+98 916 615 2270

Email

drhosseininejad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Hosseininejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, Azadegan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135913441

Phone

+98 916 615 2270

Email

drhosseininejad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Hosseininejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini Hospital, Azadegan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135913441

Phone

+98 916 615 2270

Email

drhosseininejad@yahoo.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researcher's request to conduct similar studies

From where data/document is obtainable

Request by sending an email to the responsible administrator

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

Sending an email to the responsible executive and explaining the procedure, then sending the data to her

Comments