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, rand 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 µ/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 Hosseininejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3443 5099

Email address
drhosseininejad@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 sychiatric 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.sealedenevelope.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 µ/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 unware of the type of injected drug.the medicine is already prepare 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

Khouzestan

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

cholesystit

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 angioket. Initial monitoring will include pulse oximetry, non-invasive sphygmomanometer, and electrocardiography. Initial symptoms will be recorded and treated with midazolam 0.03 drugs. mg/kg, fentanyl 2 µgr/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 µ/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 µ/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
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Postal code
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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

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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