

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of intraperitoneal ropivacaine and ketamine on pain control after cholecystectomy

Protocol summary

Study aim

Evaluation of intraperitoneal injection of Ketamine and Ropivacaine to control and reduce postoperative pain cholecystectomy and reduce the need for postoperative analgesia

Design

Two-group clinical trial, with parallel groups, double-blind, randomized, phase 3 on 120 patients. The table of random numbers will be used for randomization.

Settings and conduct

The first group includes 60 patients who will receive 20 ml of Ropivacaine 0.5%. Before removing the trocar at the end of surgery, the drug will be injected into the peritoneum, in the Trendelenburg position, to facilitate the dispersion of the drug solution in the area of the liver, diaphragm, around the gallbladder, and near the hepatodeodenum ligament. The second group consists of 60 patients who will receive 0.5 mg/kg of intraperitoneal Ketamine in 30 ml of diluted normal saline. Gallbladder and near hepatodeodenum ligament will be injected. Research site is Valiasr Hospital in Arak, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-60 years with the indication of laparoscopic cholecystectomy with a VAS score greater than or equal to 5. Exclusion criteria: allergy to Ketamine or Ropivacaine; cardiovascular, lung or mental illness; arbitrary use of any additional analgesics after surgery.

Intervention groups

In one group of patients with laparoscopic cholecystectomy, intraperitoneal injection of Ketamine will be performed and in another group, intraperitoneal injection of Ropivacaine will be performed.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054499N1**

Registration date: **2022-05-24, 1401/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

Mohammad Amin Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3869 3057

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-24, 1401/03/03

Expected recruitment end date

2022-07-15, 1401/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intraperitoneal ropivacaine and ketamine on pain control after cholecystectomy

Public title

Comparison of the effect of ropivacaine and ketamine on pain control after cholecystectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 years old Patients indicated for laparoscopic cholecystectomy All patients with a VAS score equal or greater than 5

Exclusion criteria:

Hypersensitivity to Ketamine or Ropivacaine Has cardiovascular, lung or mental illness Arbitrary use of any additional painkillers after surgery Patients indicated for open cholecystectomy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into 2 groups based on block random method in 4 and 8 formats using a table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, the data collector, and outcome assessor are unaware of the type of drug prescribed and the groupings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences,

Sardasht street

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-05-01, 1401/02/11

Ethics committee reference number

IR.ARAKMU.REC.1401.038

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K81

ICD-10 code description

Cholecystitis

Primary outcomes

1

Description

Patients' pain based on visual analog scale

Timepoint

2, 4, 8, 12, 24 hours after surgery

Method of measurement

Use visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 0.5 mg / kg intraperitoneal Ketamine diluted in 30 ml of normal saline, which will be injected into the liver space at the end of the operation before removing the trocars in the Trendelenburg position.

Category

Rehabilitation

2

Description

Control group: injection of 20 ml of 0.5% Ropivacaine, which will be injected into the liver at the end of the operation before removing the trocars in the Trendelenburg position.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Mohammad Amin Eslami

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Valiasr Hospital, Valiasr Square, Shahid Shirodi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Vice chancellor for Research, Payambar Azam
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Amir Reza Naeimi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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