Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Email address
m.eslami@arakmu.ac.ir

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 Trendlenberg position.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Mohammad Amin Eslami

Street address
Valiasr Hospital, Valiasr Squre, Shahid Shirodi Street

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Fax

Email
m.eslami@arakmu.ac.ir

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 Complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3383 8319

Email
alikamaliir@yahoo.com

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

Street address
Valiasr Hospital, Shahid Shirodi street, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Email
amirrezanaeimi@yahoo.com

Person responsible for scientific 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

Street address
Valiasr Hospital, Shahid Shirodi street, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003

Email
amirrezanaeimi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Amin Eslami

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Valiasr Hospital, Shahid Shirodi street, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
m.eslami@arakmu.ac.ir

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