

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A comparative study of free opioid anesthesia and standard general anesthesia on the complication amount cholecystectomy patient

Protocol summary

Study aim

Comparative study of anesthesia with and without drug use on complications in patients undergoing cholecystectomy

Design

This randomized clinical trial with a parallel design, none blind and has a control group. This study is randomized, phase 3 study will be performed on 63 patients who are candidates for cholecystectomy. Random blocks are used for randomization and participants are assigned to two intervention groups.

Settings and conduct

This study, which will be performed in Imam Reza Hospital of Kermanshah, is a double-blind. Researchers and participants were blinded by the allocation of study groups. Before the operation, patients will be asked for the necessary history and routine examinations and tests will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have not taken a long-acting analgesic in the last month; Patients who are not addicted. Exclusion criteria: Patients with serious chronic diseases including diabetes, tuberculosis, epilepsy; cardiovascular and .. ; Patients who have received a vaccine or antidote within 1 month prior to screening

Intervention groups

In the first intervention group, anesthesia is performed using narcotics (Sufentanil Abu Reihan Company dose of half a microgram per kilogram of body weight by injection). In the second intervention group for anesthesia of patients from a combination of magnesium infusion for auxiliary analgesia and low dose ketamine for analgesia and dexmetomidin for sympatholysis. Analgesia, anesthesia and lidocaine are used for laryngoscopy and non-irritation and ketorolac is used for pain during and after surgery.

Main outcome variables

Pain after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N177**

Registration date: **2021-10-23, 1400/08/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-23, 1400/08/01**

Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-11, 1400/07/19

Expected recruitment end date

2022-08-09, 1401/05/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of free opioid anesthesia and standard general anesthesia on the complication amount cholecystectomy patient

Public title

Comparison of anesthesia with and without drug use on complications in patients undergoing gallbladder surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have not taken a long-acting analgesic in the last month Patients who are not addicted

Exclusion criteria:

Patients with serious chronic diseases including diabetes, tuberculosis, epilepsy; Cardiovascular and .. Patients who have received a vaccine or antidote within 1 month prior to screening Patients who have received an immunosuppressive drug one month before surgery Patients who are allergic to morphine or morphine compounds Pregnant people

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The permutation random block is used for randomization. In this way, first, the total sample size and the ratio of sample size in groups are determined. Then, the number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block is 0.5. Block 4-0 for the first group and block 5-9 for the second treatment can be used. Based on the selected numbers from the table of random numbers and the determination of blocks, it is clear in which group each person who enters the study will be placed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-08-31, 1400/06/09

Ethics committee reference number

IR.KUMS.REC.1400.465

Health conditions studied

1

Description of health condition studied

Cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description

Pain after surgery

Timepoint

5 hours after surgery, discharge time

Method of measurement

Based on Visual Pain Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, anesthesia is performed using narcotics (Sufentanil Abu Reihan Company dose of half a microgram per kilogram of body weight by injection).

Category

Treatment - Drugs

2

Description

In the second intervention group for anesthesia of patients from a combination of magnesium infusion (Samen company one to two mg) for auxiliary analgesia and low dose ketamine (Retekmedica company dose of 0.2 mg per kg body weight) for analgesia and dextmetomedin for sympatholysis Analgesia, anesthesia and lidocaine (Exir company dose of 1 mg per kilogram of body weight) are used for laryngoscopy and non-irritation and ketorolac (Abu Reihan company 60 mg) is used for pain during and after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohammad Javad Alibakhshi

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Javad Alibakhshi

Position

Resident anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Alireza Ahmadi

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available