

# 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)

##### Phone

+98 83 1821 4653

##### Email address

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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mjalibakhshi@yahoo.com

## 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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rkhodarahmi@kums.ac.ir

**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

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Latest degree**  
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**Other areas of specialty/work**  
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**City**  
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**Province**  
Kermanshah  
**Postal code**  
6715847141  
**Phone**  
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**Email**  
mjalibakhshi@yahoo.com

## 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