

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effects of Dexamethasone on the prevention of elevation of C-reactive protein and pain following laparoscopic cholecystectomy

Protocol summary

Summary

Patients who are admitted with diagnosis of cholelithiasis and are candidate for laparoscopic cholecystectomy will be evaluated. 68 patients fall into two groups according to random assignment before performing cholecystectomy. Group A will receive 8 mg of intravenous dexamethasone (2 ml), 15 min before induction of anesthesia. Group B will receive 2 ml of normal saline as placebo intravenously 15 minutes before induction of anesthesia. Before surgery and 6, 12 and 24 hours after surgery, venous blood samples from patients will be taken to measure level of serum C-reactive protein (CRP) with ELISA assay. The incidence of pain is recorded with asking from patient in 3 periods of time (6th, 12th and 24th hours) after operation by two nurses of ward who are not aware of randomized groups. To assess pain intensity Visual analog scale (VAS) with a 10cm-ruler will be used and patients will indicate number of pain on the ruler. In this method zero indicates no pain and ten indicates intolerable. Outcomes including CRP, pain intensity, dosage of analgesic administration (petedin) and relationship between CRP and pain intensity will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012115364N1**

Registration date: **2011-03-07, 1389/12/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-03-07, 1389/12/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Dexamethasone on the prevention of elevation of C-reactive protein and pain following laparoscopic cholecystectomy

Public title

Effects of Dexamethasone on the prevention of elevation of C-reactive protein and pain following laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with diagnosis of cholelithiasis who are candidate for laparoscopic cholecystectomy.

Exclusion criteria: pregnancy, age under 18 or over 80

years, body mass index over 30, presence of underlying disease, associated infection, history of previous abdominal surgery, diagnosis of empyema of gallbladder, usage of steroids and opioids during last week, and all situations which anesthetic drugs administration is contraindicated in, the selected cases will be enrolled after writing consent.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Shahid Beheshti blvrd.

City

Kermanshah

Postal code

6718818838

Approval date

2010-07-13, 1389/04/22

Ethics committee reference number

672

Health conditions studied

1

Description of health condition studied

Cholelithiasis

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Pain intensity

Timepoint

6 hours, 12 hours and 24 hours after surgery

Method of measurement

visual analog scale (VAS)

2

Description

Serum Level of CRP

Timepoint

Before surgery and 6, 12 and 24 hours after surgery

Method of measurement

level of serum CRP with Elisa assay

Secondary outcomes

1

Description

Amount of analgesic required

Timepoint

If the patient expressed pain

Method of measurement

miligram

Intervention groups

1

Description

2cc intravenous normal saline

Category

Placebo

2

Description

8 mg (2cc) intravenous dexametasone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Dr Khosrow Setaishy

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology Affairs

Full name of responsible person

Farid Najafi

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research & Technology Affairs

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Khosrow Setaishy

Position

Attending and consultant in general surgery, project manager

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty