Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 in3 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

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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

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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