Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of local injection of dexamethasone with bupivacaine at pre-peritoneal laparoscopic ports on laparoscopic complications after laparoscopic cholecystectomy a randomized controlled clinical trial.

Protocol summary

Study aim
Study the effect of dexamethasone and bupivacaine pre-peritoneal injection at the site of laparoscopic ports, on complications after laparoscopic cholecystectomy

Design
Randomized parallel phase 3 placebo-controlled triple-blinded clinical trial study

Settings and conduct
In order to evaluate the effect of bupivacaine with and without dexamethasone on pain after laparoscopic cholecystectomy, in the operating room by one of the trained technicians without informing any involved researcher and investigator, in one group of bupivacaine + dexamethasone and in the other group bupivacaine+ the same amount of normal saline is prepared and injected. The severity of postoperative pain, the rate of opium usage for pain control, and the rates of nausea and vomiting are investigated.

Participants/Inclusion and exclusion criteria
The inclusion criteria are all patients undergoing laparoscopic cholecystectomy diagnosed with biliary colic or chronic cholecystitis. Criteria for not including patients in our study are the diagnosis of acute cholecystitis along with findings such as leukocytosis and high ESR and CRP, gangrene, empyema and evidence of bile in the abdominal cavity during surgery, known allergy to local anesthetics, open surgery and diabetic patients and those with dirty wounds and open cholecystectomy.

Intervention groups
In the intervention group, the dose of dexamethasone is 0.2 mg per kg of body weight. It is divided into four parts, and each part is injected around each trocar. For bupivacaine, 7 mg is injected at the lower ports and 3 mg at the upper ports. For a placebo, the same amount of normal saline based on the dexamethasone formula is mixed and injected.

Main outcome variables
The severity of postoperative pain, rates of opium usage for pain control, nausea, and vomiting

General information

Reason for update
Trial ending and updating information

Acronym

IRCT registration information
IRCT registration number: **IRCT20211008052699N1**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **prospective**

Last update: **2023-04-30, 1402/02/10**
Update count: **1**

Registration date
2021-11-29, 1400/09/08

Registrant information

Name
Mohammad Eslamian

Name of organization / entity

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Iran (Islamic Republic of)

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Email address
mr.esl67@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-30, 1400/09/09

Expected recruitment end date
2022-04-21, 1401/02/01
Actual recruitment start date
2021-11-30, 1400/09/09
Actual recruitment end date
2022-04-30, 1401/02/10
Trial completion date
2022-08-23, 1401/06/01

Scientific title
Evaluation of the effect of local injection of dexamethasone with bupivacaine at pre-peritoneal laparoscopic ports on laparoscopic complications after laparoscopic cholecystectomy a randomized controlled clinical trial.

Public title
Evaluation of dexamethasone injection on complications after gallbladder surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Laparoscopic cholecystectomy with diagnosis of biliary colic or chronic cholecystitis
Exclusion criteria:
Acute cholecystitis Presence of leukocytosis or high ESR, CRP Gangrene, empyema and evidence of bile in the abdominal cavity during surgery Known allergies to local anesthetics History of chronic pain following the use of common narcotics Open cholecystectomy Patients with immunodeficiency and diabetes Cases that have dirty wounds during the operation
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **96**
Actual sample size reached: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into two groups using the computer random-generated number method. This random distribution of patients will be done by an independent computer programmer using www.randomization.com.
Blinding (investigator's opinion)
Triple blinded
Blinding description
On the day of surgery, one of the operating room technicians trained according to the instructions and based on the site www.randomization.com prepares the medicine for the group in which the patient is accidentally placed and then the surgeon injects it only without notice to the relevant place. Dexamethasone and bupivacaine are injected into a syringe, and to hide the volume of the drug, the syringes are covered with a dark coating and the syringe is identified only based on groups A and B. Slowly The patient and the data collector and the safety and data monitoring committee also do not know what the drug was.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical sciences., Hezarjarib St., Azadi Sq
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Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-10-03, 1400/07/11
Ethics committee reference number
IR.MUI.MED.REC.1400.546

Health conditions studied

1

Description of health condition studied
Chronic cholecystitis
ICD-10 code
K81.1
ICD-10 code description
Chronic cholecystitis

2

Description of health condition studied
Postprocedural pain
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain intensity based on VAS the first 24 hours after surgery
Timepoint
24 hours after the surgery
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
The need for opium and analgesics
Timepoint
24 hours after the surgery
Method of measurement
Medical records

2

Description
Frequency of nausea, vomiting within 24 hours after surgery
Timepoint
24 hours after the surgery
Method of measurement
Medical records

Intervention groups

1

Description
Intervention group 1: After induction of general anesthesia and surgery, a peritoneal injection will be performed at the incision site of the trocars under the direct guidance of a laparoscopic camera with No. 18 branul. In the "bupivacaine + dexamethasone" group, 7 mg bupivacaine is injected at the lower ports and 3 mg bupivacaine at the upper ports. The dose of dexamethasone is then determined based on the patient's weight at 0.2 mg per kg and divided into four parts and each part is injected at the site of a port.
Category
Treatment - Drugs

2

Description
For intervention group 2: In the bupivacaine group alone, 7 mg bupivacaine will be injected at the lower ports and 3 mg bupivacaine at the upper ports. For the placebo, based on the formula used for dexamethasone and body weight, sterile injectable normal saline is used.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
Hamid Melali
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2

Recruitment center
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3

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Eslamian
Position
Assistant Professor
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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