# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 May 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**

**Country**
Iran (Islamic Republic of)

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**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
**City**
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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Sonbolestan St, Ebn-Sina Ave
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### 2

**Recruitment center**
**Name of 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
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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**
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
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Mohammad Eslamian
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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