Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the efficacy of Intraperitoneal Dexamethasone with intravenous Dexamethasone on Nausea and Vomiting after Laparoscopic Cholecystectomy

Protocol summary

Study aim
Evaluation the level of Nausea and Vomitting after Laparoscopic Cholecystectomy with using Intrapritoneal injection of Dexamethasone in compare to its Intravenous form

Design
Randomized, phase 3 clinical trial with two parallel groups, with control group, double- blind, postoperative care, on 80 patients.

Settings and conduct
This study is a double-blind randomized controlled clinical trial in which the target population will be patients who are candidates for laparoscopic cholecystectomy at Al-Zahra Hospital in Isfahan. Patients are divided into three groups by simple random allocation. After being placed on the operating table and connecting the monitor to the patient, each group is injected with allocated drug. The patient's vital signs and hemodynamic status are controlled and recorded before, during, and after the operation. The intervention groups are coded, so the injector, clinical caregiver, surgeon, and patient are unaware of the injected intervention and are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all patients aged 18 to 65 years who are candidates for laparoscopic cholecystectomy in ASA class I and II anesthesia . Exclusion criteria: Preoperative nausea and vomiting and pregnancy, allergic to corticosteroids and use it before surgery.

Intervention groups
After removing the last clamp,Group A receives 2cc intrapritoneal Normal saline and 8mg intravenous Dexamethasone.Group B,receives 2cc intravenous Normal saline and 8mg intrapritoneal Dexamethasone.Group C receives 2cc intravenous Normal saline and 2cc intrapritoneal Normal saline.

Main outcome variables
Nausea and Vomitting, Pain, Blood pressure, Heart rate, Blood oxygen saturation and patients satisfaction.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N25**
Registration date: **2020-09-20, 1399/06/30**
Registration timing: **prospective**

Last update: **2020-09-20, 1399/06/30**
Update count: **0**

Registration date
2020-09-20, 1399/06/30

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Intraperitoneal Dexamethasone with intravenous Dexamethasone on Nausea and Vomiting after Laparoscopic Cholecystectomy

Public title
Effect of Dexamethasone on Nausea and Vomitting after cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age above 18 years Candidate for laparoscopic Cholecystectomy Physical Situation ASAP and ASA2 Agreement on Participation in Study
Exclusion criteria:
Pregnancy Allergy and Reaction to Corticosteroids Using corticosteroids before Surgery Existing of Nausea and Vomitting before Surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done simply in which patients will enter into groups A, B, and C respectively, according to their time of admission, then the next three patients will enter into these groups in the same way to complete of number of patients in each three groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs and Placebo are prepared and coded in the same appearance. The patient, the injecting specialist, the surgeon, and the respondent are unaware of the contents of the injected drug and are blind.
Placebo
Used
Assignment
Parallel
Other design features
In this study, for the first time, we used Intrapritoneal Dexamethasone in laparoscopic cholecystectomy.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan university of Medical sciences
Street address
Hezar jarib street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-07-30, 1399/05/09
Ethics committee reference number
IR.MUI.MED.REC.1399.350

Health conditions studied

1

Description of health condition studied
Laparoscopic Cholecystectomy
ICD-10 code
بیماریهای
ICD-10 code description
K00-K93

Primary outcomes

1

Description
Nausea
Timepoint
After entry to Recovery, every 15 minute until the exit of recovery and then 2,4,8,12 and 24 hours in the first 24 hour after surgery in all 3 group
Method of measurement
Ask the patient

2

Description
Vomitting
Timepoint
After entry to Recovery, every 15 minute until the exit of recovery and then 2,4,8,12 and 24 hours in the first 24 hour after surgery in all 3 group
Method of measurement
Ask the patient

3

Description
Systolic blood pressure
Timepoint
Before Anesthesia, After Anesthesia and after injection of Dexamethasone at 1,5,10 minutes and every 15 minute until the end of surgery in all groups.
Method of measurement
Non invasive blood pressure measurement

4

Description
Diastolic blood pressure
Timepoint
Before Anesthesia, After Anesthesia and after injection of Dexamethasone at 1,5,10 minutes and every 15 minute until the end of surgery in all groups.
Method of measurement
Non invasive blood pressure measurement

5

Description
Heart rate
Timepoint
Before Anesthesia, After Anesthesia and after injection of Dexamethasone at 1,5,10 minutes and every 15 minute until the end of surgery in all groups.
Method of measurement
ECG Monitoring

6

Description
Oxygen saturation
Timepoint
Before Anesthesia, After Anesthesia and after injection of Dexamethasone at 1,5,10 minutes and every 15 minute until the end of surgery in all groups.
Method of measurement
Pulse oximeter

7

Description
Pain
Timepoint
After entry to Recovery, every 15 minute until the exit of recovery and then 2,4,8,12 and 24 hours in the first 24 hour after surgery in all 3 group
Method of measurement
VAS score system

8

Description
Patients satisfaction
Timepoint
First 24 hour after surgery
Method of measurement
Likert scale system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Patients receive 2cc intrapritoneal Normal saline and 8mg intravenous Dexamethasone in base of Gallbladder after removing last clamp and exiting laparoscope.
Category
Prevention

2

Description
Intervention group B: Patients receive 2cc intravenous Normal saline and 8mg intrapritoneal Dexamethasone in base of Gallbladder after removing last clamp and exiting laparoscope.
Category
Prevention

3

Description
Control group: Patients receive 2cc intravenous Normal saline and 2cc intrapritoneal Normal saline in base of Gallbladder after removing last clamp and exiting laparoscope.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Alzahra Hospital
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Sponsors / Funding sources

1

Sponsor
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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
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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