

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of intravenous dexamethazone on nausea and vomiting after laparoscopic cholecystectomy operation

Protocol summary

Summary

(1) Objective: to assess the effect of intravenous dexamethasone for prevention of nausea and vomiting after laparoscopic cholecystectomy in patients, (2) Design: randomized, double-blind, placebo-controlled, single-center, phase two trials, (3) Setting and conduct: injection of 8 milligram dexamethasone intravenously 30 minutes to an hour before surgery in patient group and 2 milliliter of saline in controls. After that, questioning patients about complain of nausea and vomiting and recording in the questionnaire. During this time, if they complain of nausea and vomiting, 10 milligram metoclopramide will be administered intravenously, (4) Participants including major eligibility criteria: all patients with biliary colics and uncomplicated cholelithiasis undergoing laparoscopic cholecystectomy referring Zahedan Ali-ebn Abi Talib Hospital; Major eligibility criteria: consent to participate in the study; no intake of steroid drugs 48 hours before surgery; not diabetic; no contraindication of dexamethasone usage; not pregnant; Major exclusion criteria: diabetes; contraindications of dexamethasone; pregnancy, (5) Intervention: injection of dexamethasone before surgery, (6) main outcome measures (variables): nausea and vomiting after laparoscopic cholecystectomy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121325515N1**
Registration date: **2016-05-21, 1395/03/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Yaha Ehsanollahi

Name of organization / entity

Zahedan Medical University of Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-18, 1394/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous dexamethazone on nausea and vomiting after laparoscopic cholecystectomy operation

Public title

Effect of intravenous dexamethazone on nausea and vomiting after cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Terms of Inclusion: consent to participate in the study; no intake of steroid drugs 48 hours before surgery; not diabetic; no contraindication of dexamethasone intake;

not pregnant
Terms of exclusion: no consent to participate in the study; intake of steroid drugs 48 hours before surgery; diabetic; contraindication of dexamethasone intake; pregnancy

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

Ethics Committee of Zahedan Medical University of Science

Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

Approval date

2015-06-19, 1394/03/29

Ethics committee reference number

IR.zaums.res.1394.329

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K81, K81-0

ICD-10 code description

Cholecystitis

Primary outcomes

1

Description

Nausea

Timepoint

Up to 24 hours after surgery in intervals of every 4 hours

Method of measurement

Questioning patients about complain of nausea and recorded in the questionnaire

2

Description

Vomitting

Timepoint

Up to 24 hours after surgery in intervals of every 4 hours

Method of measurement

Questioning patients about complain of vomiting and recorded in the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: administration single dose of 8 milligram dexamethasone intravenously 30 minutes to an one hour before surgery

Category

Treatment - Drugs

2

Description

Control group: administration single dose of 2 milliliter normal saline intravenously 30 minutes to an one hour before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Yahya Ehsanollahi

Street address

Surgery Department, Zahedan Ali-ebn Abi Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

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, Zahedan University of Medical Sciences

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**

Zahedan Medical University

Full name of responsible person

Yahya Ehsanollahi

Position

Surgery Residence

Other areas of specialty/work**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Blvd, Dr.Hesabi Sq., Daneshgah Ave., Zahedan

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Person responsible for scientific

inquiries

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Full name of responsible person

Dr. Alireza Khazaei

Position

Associate Professor of Surgery

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Zahedan University of Medical Sciences

Full name of responsible person

Yahya Ehsanollahi

Position

Surgery Resident

Other areas of specialty/work**Street address**

Surgery Department, Ali-ebn Abi Taleb Hospital, Salamat Blvd., Dr.Hesabi Sq., Daneshgah Ave., Zahedan

City

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Postal code**Phone**

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Fax**Email****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