

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluating the effects of using a single dose of dexamethasone and chlorpheniramine alone and together in the prevention of postoperative nausea and pain in patients undergoing laparoscopic cholecystectomy

Protocol summary

Summary

The purpose of this study was to evaluate the efficacy of dexamethasone and chlorpheniramine alone and together in prevention of postoperative nausea and pain after laparoscopic cholecystectomy. This single centered double-blinded clinical trial was performed on 100 patients undergoing laparoscopic cholecystectomy. Patients candidate for laparoscopic cholecystectomy were included to the study without age limit if they had written consent. Opium addiction, patients who received antiemetic agents during 24 hrs before the operation and patients who received steroids and antihistamines were excluded from the study. Patients were randomly divided into 4 grouse based on the selected colored cards. Studied interventions in all treatment groups was performed 30 minutes before the surgery. Group 1 received 8 mg of dexamethasone, group 2 received a vial of chlorpheniramine and group 3 received both dexamethasone and chlorpheniramine , and the group 4 received neither drug placebo. The study was double-blinded neither the subjects nor the investigators were aware of the distribution of the drugs. The postoperative pain was recorded from one to ten with visual analogue scale every 2 hrs to 12 hrs after the remove of tracheal tube. Nausea was evaluated as a secondary variable on the basis of scoring criteria. At the end the results of each group was compared to others.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030126853N1**
Registration date: **2016-05-01, 1395/02/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-01, 1395/02/12

Registrant information

Name

Hoda Hekmat

Name of organization / entity

Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of using a single dose of dexamethasone and chlorpheniramine alone and together in the prevention of postoperative nausea and pain in patients undergoing laparoscopic cholecystectomy

Public title

Evaluating the effects of using of dexamethasone and chlorpheniramine in the prevention of postoperative nausea and pain in patients undergoing Laparoscopic Gallbladder Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Undergoing elective surgery laparoscopic cholecystectomy. Exclusion criteria: Opium addiction; liver disorders; tuberculosis or latent tuberculosis; Hypothyroidism; using Steroids, Antihistamines or Digoxin, Oral contraceptive pill and Amphotericin; diabetes melitus; fungal infections; hyper tension; morbid obesity; the use of antiemetic agents during 24 hrs before surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

random sampling is based on the selected colored cards.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Postal code

3419759811

Approval date

2016-02-23, 1394/12/04

Ethics committee reference number

IR.QUMS.REC.1394.277

Health conditions studied

1

Description of health condition studied

Nausea & Vomiting , Following laparoscopic cholecystectomy

ICD-10 code

K91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

Primary outcomes

1

Description

pain

Timepoint

Every 2 to 12 hours after the removal of tracheal tube

Method of measurement

based on the visual analogue scales (VAS)

Secondary outcomes

1

Description

Nausea

Timepoint

Every 2 to 12 hours after the removal of tracheal tube

Method of measurement

Based on observation and scoring criteria

Intervention groups

1

Description

Group 1 received 8 mg of dexamethasone(DarouPakhsh) 30 minutes before the operation.

Category

Prevention

2

Description

Group 2 received a vial of chlorpheniramine (Alborz Darou) 30 minutes before the operation.

Category

Prevention

3

Description

Group 3 received a vial of chlorpheniramine(Alborz Darou) along with 8 mag of dexamethasone(DarouPakhsh) 30 minutes before the operation.

Category

Prevention

4

Description

group 4 (control group) received no drugs.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Velayat Educational and Treatment Center

Full name of responsible person

Dr. Hossein Parsa

Street address

Velayat Hospital, Taavon Sq., 22 Bahaman Blvd,
Elahieh

City

Qazvin

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research Qazvin University of
Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Blvd

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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

Vice Chancellor for research Qazvin 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**

Velayat educational and treatment center

Full name of responsible person

Dr. Hoda Hekmat

Position

Assistant of Surgery

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University Of Medical Sciences

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Position

Assistant Professor of Vascular Surgery

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Velayat educational and treatment center

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Position

Assistant of Surgery

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City

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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