Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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; tuberclosis or latent tuberclosis; 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
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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
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Person responsible for scientific inquiries

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00
Fax
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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