Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of prophylactic anti-emetic effect of Dexamethasone in patients undergoing elective laparoscopic cholecystectomy in comparison with Metoclopramide and placebo.

Protocol summary

Summary

To evaluate the prophylactic anti-emetic effect of dexamethasone we are going to run a double blinded placebo controlled clinical trial in Shahid Mostafa Khomeini Hospital, Tehran, Iran. In this study all patients with an age ranging 18 to 60 years, who are undergoing general anesthesia for elective laparoscopic cholecystectomy and consent to enroll in this study, will participate. However patients who have a history of motion sickness, any intestinal diseases or those who had received any anti-emetic agents within 24h before surgery will be excluded. Target sample size for this study is 160 patients and these enrolled patients will be allocated randomly to three groups of intervention, control intervention and placebo. Patients in intervention group will receive 8 mg of dexamethasone intravenously just before induction of anesthesia while those who are in control group will receive 10 mg of metoclopramide and those who are in placebo group only receive Normal Saline intravenously. For all these patients each episodes of post-operative vomit or sensation of post-operative nausea will be recorded 7 times during first 24 hour after surgical recovery without knowledge of if or which anti-emetic agents the patient had received. The anesthetic condition for all enrolled patient will be standardized. Laparoscopic cholecystectomies will perform as a standard procedure with pre-operative cholangiography and will be similar for all patients. The duration of the surgery, anesthesia, and CO2 insufflation will be recorded as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112088329N1**
Registration date: **2012-01-06, 1390/10/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-06, 1390/10/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shahid Mostafa Khomeini Hospital, Shahed UniversityMD dissertation

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-03-12, 1390/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylactic anti-emetic effect of Dexamethasone in patients undergoing elective

laparoscopic cholecystectomy in comparison with Metoclopramide and placebo.

Public title
Effect of Dexamethasone on prophylaxis of nausea and vomiting after laparoscopic cholecystectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: Patients and age ranging 18 to 60 years who undergo general anesthesia for elective laparoscopic cholecystectomy in Mostafa Khomeini hospital. Exclusion criteria: Patients who have a history of motion sickness; Patients who have any intestinal diseases ;Patients who had received any anti-emetic agents within 24h before surgery; pregnant or breast-feeding women; patients who have evidence of hepatic dysfunction
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **160**
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
Shahed University,Faculty of Medicine
Street address
Shahid Mostafa KHomeini Hospital,Italia St. , Felestin SQ
City
Tehran
Postal code
Approval date
2008-08-20, 1387/05/30
Ethics committee reference number
p162/78

Health conditions studied

1

Description of health condition studied
Nausea and Vomiting after cholecystectomy
ICD-10 code
K91.5
ICD-10 code description
Postcholecystectomy syndrome

2

Description of health condition studied
Post-Operative Vomiting
ICD-10 code
K91.0
ICD-10 code description
Vomiting following gastrointestinal surgery

Primary outcomes

1

Description
Episodes of post-operative Vomit
Timepoint
Time 0 until 24 hours after recovery form General anesthesia
Method of measurement
Asking from patients

Secondary outcomes

1

Description
sensation of post-operative nausea
Timepoint
0 -24 hours after recovery from general anesthesia
Method of measurement
visual scale

Intervention groups

1

Description
Ampul Dexamethasone 8 mg IV for intervention group
Category
Prevention

2

Description
Ampul Metoclopramide 10mg IV for control group
Category
Prevention

3

Description

Ampul Normal Saline (0.9%) IV

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Alireza Khalaj

Street address

Shahid Mostafa Khomeini Hospital, Italia St, Felestin Sq, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Deputy of Research

Street address

Mostafa Khomeini Hospital, Italia St, Felestin Sq.

City

Tehran

Grant name

اعتبار مربوط به پایان نامه ی پزشکی ، دانشکده پزشکی ، دانشگاه شاهد.

Grant code / Reference number

p 162/78

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

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Full name of responsible person

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Position

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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