Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of diphenhydramine and granisetron on the prevention of postoperative nausea and vomiting and pain after laparoscopic cholecystectomy

Protocol summary

Study aim

The effect of diphenhydramine and granisetron on the prevention of postoperative nausea and vomiting and pain after laparoscopic cholecystectomy.

Design

A total of 120 patients will be selected based on studies and statistical calculations that meet the inclusion criteria after surgery and the patient is discharged from anesthesia and then divided into two groups of intervention and control. The intervention group will receive granisetron and the control group will receive diphenhydramine. The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

The study will be conducted at the recovery ward of Tabriz Imam Reza Hospital.In the intervention group,immediately after extubation,Granisetron will be injected at a dose of 3mg interavenously and in the control group,Diphenhydramin will be injected at a dose of 50mg.Then the variables of nausea,vomiting and pain will be reviewed and recorded in both groups by anethesiologist.Postoperative nausea and vomiting will be reviewed and recorded at recovery at 3,6 and 24 hours after operation based on scores(0=no nausae and vomiting, 1=nausea,2=vomiting,3=vomiting more than 2times).Pain severity at 5,10,15,20 seconds after injection will be evaluated by four digit verbal rating scale.In this study both patiants and anesthesiologist are blinded.

Participants/Inclusion and exclusion criteria

Entrance: All of Patients who Being a Candidate for Elective Surgery and Based on ASA Classification are 1 or 2 ASA Class. Exit: Patients under Prescription of anti-nausea Drugs in the last 24 hours; Patients with Cardiovascular, Hepatic , Kidney ,blood pressure and hyperadiposis Disease; pregnant women and during menstruation .

Intervention groups

Granisetron will be used in the intervention group and Diphenhydramine will be used in the control group

Main outcome variables

Severity of pain Severity of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150125020795N7**
Registration date: **2019-11-11, 1398/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-11, 1398/08/20**
Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name
Samad Golzari
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 3556 6183
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golzaris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of diphenhydramine and granisetron on the prevention of postoperative nausea and vomiting and pain after laparoscopic cholecystectomy

Public title

Effect of diphenhydramine and granisetron on the prevention of postoperative nausea and vomiting and pain after laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All of Patients at age of 18 to 59 who Being a Candidate for Elective Surgery and Based on ASA Classification are 1 or 2 ASA Class.

Exclusion criteria:

Patients under Prescription of anti-nausea Drugs in the last 24 hours. Patients with Cardiovascular, Hepatic , Kidney ,blood pressure and hyperadiposis Disease pregnant women and during menstruation

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling is done by easy burst method and according to patient referral to operating room. Randomization method is pre and post accidental blocks and will be done by Randlist software.

Blinding (investigator's opinion)

Double blinded

Blinding description

All of Patients do not Know about used Drugs in this Study. and the anesthesiologist who evaluated clinical response to administerated drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculity of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.TBZMED.REC.1398.431

Health conditions studied

1

Description of health condition studied

Postoperative nausea and vomiting

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

2

Description of health condition studied

Postoperative pain

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Severity of postoperative nausea and vomiting

Timepoint

Recovery and at 3, 6, and 24 h postoperatively

Method of measurement

scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

Secondary outcomes

1

Description
Severity of pain after injection of diphenhydramine and granisetron
Timepoint
Amount of pain evaluate on 5, 10, 15 and 20 seconds after injection of diphenhydramine and granisetron
Method of measurement
Four Numerical Verbal Rating Scale

Intervention groups

1

Description
Intervention group: Group 1, will recieve 3 mg IV granisetron before induction of anesthesia
Category
Treatment - Drugs

2

Description
Control group: Group 1, will recieve50 mg IV diphenhydramine before induction of anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Samad Eslaam Jamal Golzari
Street address
Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Joyban
Street address
Vice chancellor for research, Daneshgah street, Tabriz
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5165665931
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Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Samad Eslam Jamal Golzari
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used
There will be no specific limitations to the utilization of the data .

From where data/document is obtainable
Dr .Samad Eslam Jamal Golzari, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 413 3341994 Fax+98 41 33341994 golzaris@tbzmed.ac.ir

What processes are involved for a request to access data/document
Correspondence through email only

Comments