Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized double-blinded clinical trial: The effect of Granisetron on pain of Propofol injection in patients candidate for elective laparoscopic cholecystectomy

Protocol summary

Summary

The purpose of this investigation is the assessment of the effect of Granisetron on pain of Propofol injection. This investigation is a double-blinded randomized clinical trial on 30 patients between ages 20 and 50 years of both genders who have ASA Class 1, 2 and are candidates for elective laparoscopic cholecystectomy. In the cases of past medical history of neurological diseases, chronic pain syndrome, thrombophlebitis, advanced systemic disease such as advanced diabetes, any vascular disease and contraindications of Granisetron or Propofol, the patients will be excluded. Neither the patients nor the interventionist were aware whether the solution injected in each hand is Granisetron or placebo. A 22 gauge cannula will be inserted in the dorsal vein of each hand. One hundred ml normal saline is infused over 10 minutes through each cannula. Venous drainage will be occluded by tourniquet. The patients receive 2ml (2mg) Granisetron via one cannula and 2ml normal saline through the other cannula on the opposite hand simultaneously. The tourniquets are then removed and 2ml Propofol will be infused with the same infusion rate in both hands. The patients will be inquired about pain or discomfort at the injection site and the pain will be scored based on Numeric Rating Scale. Verbal answers or behavioral signs (such as facial changes, arm withdrawal, tearing ...) will all be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404095175N12**
Registration date: **2014-05-08, 1393/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-08, 1393/02/18

Registrant information

Name
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Name of organization / entity
Dr. Shariati Hospital
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-04-19, 1393/01/30

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized double-blinded clinical trial: The effect of Granisetron on pain of Propofol injection in patients candidate for elective laparoscopic cholecystectomy

Public title

The effect of Granisetron on pain of Propofol injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Ages between 20 and 50; ASA class 1, 2; Candidate for elective laparoscopic cholecystectomy
Exclusion criteria: Past medical history of neurological disease; Chronic pain syndrome; Thrombophlebitis; Advanced systemic disease such as advanced diabetes; Any vascular disease; Any contraindication for Granisetron or Propofol injection

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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, Faculty of Medicine, Tehran University of Medical Sciences

Street address

Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City

Tehran

Postal code

Approval date

2013-08-21, 1392/05/30

Ethics committee reference number

92/130/1070/د

Health conditions studied

1

Description of health condition studied

Relation between elective laparoscopic cholecystectomy pain Propofol injection in patients candidate for and Granisetron

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity

Timepoint

During injection

Method of measurement

Numeric Rating Scale mentioned by the patient

Secondary outcomes

1

Description

Postoperative Nausea and Vomiting

Timepoint

In the recovery room

Method of measurement

Nausea and vomiting expressed by the patient

Intervention groups

1

Description

Control group (30 hands) which receive normal saline before Propofol injection.

Category

Placebo

2

Description

Intervention group (30 hands) which receive Granisetron before Propofol injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr. Shahin Akhondzadeh
Street address
Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences and Health Services
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

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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