

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Prophylactic Single Dose of Vitamin C on Postoperative Pain of Laparoscopic Cholecystectomy Surgery.

Protocol summary

Summary

In this study, patients are divided into two randomized groups. The intervention group will be administered 2gr of vit C while the control group will receive 2gr of Normal Saline serum. Both administrations will take place 60 minutes before induction of anaesthesia. After Performing Laparoscopic cholecystectomy, both Groups will receive 1gr of Apotel(Paracetamol) every 8 hrs, first dose being administered at recovery room. Furthermore Patients who require more analgesics (VAS>3) will receive Pethidine(25mg). The amounts of analgesics (based on findings in patients dossier), Patients pain score(based on VAS scoring system) in recovery room and 2,6,12 and 24 hrs after the surgery And in addition, Patients Pruritis Nausea vomiting and drowsiness will be Documented in the checklist by the questioner who doesn't know about groups. In this study, questioner and patient's don't know about groups and drugs, so it's a double blind study. Outcomes of the study will be analyzed by SPSS software based on aforementioned parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051533159N2**

Registration date: **2017-09-18, 1396/06/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-18, 1396/06/27

Registrant information

Name

Alireza Negahi

Name of organization / entity

Iran university of medical sciences, Rasool Akram hospital

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Prophylactic Single Dose of Vitamin C on Postoperative Pain of Laparoscopic Cholecystectomy Surgery.

Public title

effect of pain prevention of vit-C on gallbladder surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who need Laparoscopic Cholecystectomy. Exclusion Criteria: 1; Patients who don't agree to cooperate in this clinical trial. 2; Patients who have allergy to Pethidine. 3; History of opium addiction. 4; History of sleep Apnea. 5; History of severe Asthma. 6; Patients who refer with acute cholecystitis. 7; Patients

who used NSAID in last 24h. 8;Patient who are not Cachectic.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
"Randomization" A random sequence like AABB-ABAB-...created, and the patient by the number 1-80 will be placed in two same group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science

Street address

Tehran-Hemmat Highway-Iran University of Medical Science

City

Tehran

Postal code

Approval date

2015-10-23, 1394/08/01

Ethics committee reference number

IR.IUMS.FMD.REC.1394.8921215040

Health conditions studied

1

Description of health condition studied

Calculus of gallbladder without cholecystitis

ICD-10 code

K80.2

ICD-10 code description

Cholecystolithiasis,Cholelithiasis Colic (recurrent) of gallbladder,Gallstone (impacted) of gallbladder.

Primary outcomes

1

Description

postoperative pain.

Timepoint

0-24hrs after surgery.

Method of measurement

pain score(based on VAS scoring system)

Secondary outcomes

1

Description

pruritus

Timepoint

0-24hrs after surgery.

Method of measurement

patient expression with none,slight,intermediate and severe words

2

Description

Nausea

Timepoint

0-24hrs after surgery.

Method of measurement

patient expression with Yes or No.

3

Description

Vomiting

Timepoint

0-24hrs after surgery.

Method of measurement

Patient expression about number of vomitting.

4

Description

consciousness

Timepoint

0-24hrs after surgery.

Method of measurement

1-agitated, 2-cooperate, 3-responsive to orders, 5-slow responsive to stimulation 6-Non Responsive.

Intervention groups

1

Description

intervention group:2gr IV VitC 60 minutes before induction of anaesthesia. control group:2gr IV Normal Saline 60 minutes before induction of anaesthesia.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Dr Alireza Negahi

Street address

Niayesh street, Sattarkhan street.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Science

Full name of responsible person

Reza Latifian

Street address

Rasool Akram Hospital-Surgery ward

City

Tehran

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, Iran University of Medical Science

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

Iran University of Medical Science

Full name of responsible person

Reza Latifian

Position

Medical Intern

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

General Surgeon

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Other areas of specialty/work

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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