

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of 2 grams vitamin C single dose IV injection compare with 20 ml of normal saline injection half an hour before laparoscopic cholecystectomy in pain and the patient's postoperative total opium usage in Shariati Hospital in 1393

Protocol summary

Summary

In order to understand the effect of vitamin C injection before surgery in pain control of the patients, 110 patients who are not drug abuser and are candidate for laparoscopic cholecystectomy are randomizely divided in to two groups. Cases in the intervention group will receive injections of 2 grams of vitamin C before surgery and after anesthesia and then undergo the operation. Cases in the control group will receive 20 ml intravenous normal Saline as placebo before the operation. Drugs and placebos are placed into similar boxes and will be sealed on patient's record. Both surgeon and patient will be unaware of the applied drugs. Chief Physician will perform the analysis of the results meanwhile he himself is unaware of the randomly selected cases receiving the drugs. In recovery room, surgeon will apply Narcotic Fentanyl injection pump (patient-controlled anesthesia) for both groups. Pumps would inject 1 Micro gram Fentanyl every time and will stop injecting for ten minutes afterwards. Total dose of applied Narcotics after six and twenty hours after operation will be extracted from the pump and compared together. Every six hours after operation, Patients' pain level will be measured by trained nurses using pain-rulers. Existing the nausea and vomiting will be recorded as Yes or No after 6 to 24 hours after the operation for comparison. Patients' satisfaction form will be completed prior to the patients' discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040612918N1**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Sara Emami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5534 3400

Email address

s_emami@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Faculty of medicine of Tehran University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 2 grams vitamin C single dose IV injection compare with 20 ml of normal saline injection half an hour before laparoscopic cholecystectomy in pain and the patient's postoperative total opium usage in Shariati

Public title

The effect of vitamin C injection before surgery in patient's pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who are considered for laparoscopic cholecystectomy (Laparoscopic surgery due to biliary Colic or cholecystitis) Exclusion Criteria: Patients who are allergic to Narcotics or abusing drugs will be excluded from the study. In the case of necessity for simultaneous surgery, the patient will be excluded from the study. During 24- hour follow-up, Naloxone will be provided for the patients, and if patients' respiratory rate drops below 12, PCA will be stopped and patient will be excluded from the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research and technology center of Tehran University of Medical Sciences

Street address

Poorsina street, faculty of medicine of Tehran University of Medical Sciences

City

Tehran

Postal code

1417613151

Approval date

2014-03-31, 1393/01/11

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Cholecystitis

ICD-10 code

k81.9

ICD-10 code description

Cholecystitis unspecified

2**Description of health condition studied**

post op use of opium

ICD-10 code

y45.0

ICD-10 code description

Opioids and related analgesics

3**Description of health condition studied**

postoperative pain

ICD-10 code

r 10

ICD-10 code description

abdominal and pelvic pain

4**Description of health condition studied**

post operative nausea and vomiting

ICD-10 code

r11

ICD-10 code description

Nausea and vomiting

5**Description of health condition studied**

surgical wound infection

ICD-10 code

t81.4

ICD-10 code description

Infection following a procedure, not elsewhere classified

6**Description of health condition studied**

calculus of gallbladder

ICD-10 code

k80.0

ICD-10 code description

calculus of gallbladder with acute cholecystitis

7**Description of health condition studied**

calculus of gallbladder without cholecystitis

ICD-10 code

k80.2
ICD-10 code description
 calculus of ballblader without cholecystitis

8

Description of health condition studied
 calculus of gallbladder with other cholecystitis

ICD-10 code
 k80.1

ICD-10 code description
 calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description
 amount of opium used

Timepoint
 6 and 24 hours after surgery

Method of measurement
 patient controlled anesthesia

Secondary outcomes

1

Description
 nausea and vomiting

Timepoint
 every 6 hours

Method of measurement
 visual analogue scale

2

Description
 wound infection

Timepoint
 after 7 days

Method of measurement
 physical examination

3

Description
 patient satisfaction

Timepoint
 after 24 hours

Method of measurement
 sf 12 questionair

4

Description
 urinary retention

Timepoint
 during 24 hours

Method of measurement
 examination

Intervention groups

1

Description
 The intervention is one single dose of 2 grams of vitamin c of Osve pharmacological factory that made in IRAN ,that is equal to 4 vials of vitamin c that diluted with normal saline up to 20 cc and intravenously injected in the operation room after general anesthesia

Category
 Treatment - Drugs

2

Description
 In the control group 20 cc normal saline injected intravenously after general anesthesia before surgery

Category
 Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
 Surgery ward of Dr Shariati Hospital

Full name of responsible person
 Sara Emami

Street address
 North Karegar street, Jalale Al Ahmad Highway, Tehran

City
 Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
 Faculty of medicine of Tehran University of Medical Siences

Full name of responsible person
 Hajar Moammaee

Street address
 Poorsina street, Tehran

City
 Tehran

Grant name

Grant code / Reference number

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

Title of funding source
 Faculty of medicine of Tehran University of Medical Siences

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***Postal code****Phone**

+98 21 8490 2450

Fax**Email**

khorgami@gmail.com

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Dr Shariati Hospital, surgery ward

Full name of responsible person

Sara Emami

Position

surgery resident

Other areas of specialty/work**Street address**

North Karegar street, Jalal Al Ahmad Highway

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Dr Shariati hospital, surgery ward

Full name of responsible person

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Position

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Dr Shariati hospital

Full name of responsible person

Dr Zhamak Khorgami

Position

General surgeon, associate professor

Other areas of specialty/work**Street address**

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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*