

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of Continous TAP block on post operative morphine sulphate consumption after elective laparoscopic cholecystectomy in patients of Shariati Hospital

Protocol summary

Summary

The aim of this study is to determine the effect of continuous TAP Block on opioid intake after surgery in patients undergoing laparoscopic cholecystectomy. Inclusion criteria consist of age 25 to 60 years; class 1 and 2 ASA that are candidate for laparoscopic cholecystectomy; no history of drug addiction; no history of allergy to study medications; no mental disorders; no coagulopathy; no hepatomegaly nor splenomegaly; no chronic pain disorder. Exclusion criteria consist of the patient determent; surgery time more than two hours; any intraoperative complication and failure of blocks. The patients were randomly divided into two groups of 17 people. In the intervention group continuous TAP block with catheter insertion and PCA morphine is considered. After surgery in the recovery room and 2, 6, 12 and 24 hours later in patients with NRS> 3, 16cc bupivacaine 0.25% prescribed. PCA morphine for pain control is considered in the control group. Outcomes included total amount of opioid consumption, pain intensity, duration of hospitalization, complications, time of the first injection of opioid with PCA and the first injection of drug through the catheter that are evaluated and analyzed.

General information

Acronym

TAP Block: transverse abdominis plane block

IRCT registration information

IRCT registration number: **IRCT2016110630735N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Continous TAP block on post operative morphine sulphate consumption after elective laparoscopic cholecystectomy in patients of Shariati Hospital

Public title

The effect of Abdominal nerves block on post operative morphine consumption after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria consist of age 25 to 60 years; class 1 and 2 ASA that are candidate for laparoscopic cholecystectomy; no history of drug addiction; no history of allergy to study medications; no mental disorders; no coagulopathy; no hepatomegaly nor splenomegaly; no chronic pain disorder. Exclusion criteria: the patient deterrent; surgery time more than two hours; any intraoperative complication and failure of blocks.

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee, faculty of medicine of Tehran
University of medical science

Street address

Tehran university of medical science, faculty of
medicine, Poorsina street, Keshavarz avenue

City

Tehran

Postal code

1411713135

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

IR.TUMS.REC.1394.634

Health conditions studied

1

Description of health condition studied

Elective laparoscopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description

Pain

Timepoint

Immediately after surgery in the recovery room and 2, 6,
12, 24 hours after surgery

Method of measurement

NRS (Numerical Rating Scale)

2

Description

Post operative morphin sulphate consumption

Timepoint

0, 2, 6, 12, 24 hours after surgery

Method of measurement

milligram

Secondary outcomes

1

Description

Post operative side effects

Timepoint

0, 2, 6, 12, 24 hours after surgery

Method of measurement

Patient Medical Records

2

Description

Duration of hospital stay

Timepoint

Discharge time

Method of measurement

Patient Medical Records

Intervention groups

1

Description

intervention Groups: in the intervention group TAP block with 20cc bupivacaine 0.5% and catheterization is performed in the same place. Then 10 mL of bupivacaine 0.25% is injected through the catheter if NRS>3 after 2, 6, 12, 18 hours after surgery. The PCA with morphine 1cc = 1mg stay there all the time.

Category

Treatment - Drugs

2

Description

Control group: after surgery just under PCA with morphine sulphate 1cc=1mg and record NRS score at 2, 6, 12, 24 hours after surgery and total morphin consumption

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Ali Movafegh-professor of anesthesiology

Street address

Shariati hospital, North Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Faculty of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

Faculty of Medicine, Tehran University of Medical sciences, Poorsina street, Keshavarz avenue

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 of research, Faculty of Medicine, Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Elham Naseh

Position

MD, Resident of Anesthesiology

Other areas of specialty/work

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Position

Professor of Anesthesiology

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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