Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 determent; 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 cmmittee,faculty of medicine of Tehran University of mdical science
Street address
Tehran universiy 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
Immidiatly 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 anestheiology
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Shariati hospital, North Kargar St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chanceller of research, Faculty of Medicine, Tehran University of Medical Siences
Full name of responsible person
Dr. Shahin Akhoondzadeh
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Faculty of Medicine,Tehran University of Medical sciences, Poorsina street, Keshavarz avenue
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chanceller of research, Faculty of Medicine, 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

Person responsible for general inquiries

Contact
Name of organization / entity
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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