

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the efficacy of TAP Block and Epidural A. on post operative stress response of elective laparoscopic cholecystectomy surgery in shariati hospital -1393

Protocol summary

Summary

This study is a clinical trial to compare the two methods of nerve blocks TAP BLOCK and Epidural Anesthesia on stress responses of 52 patients undergoing elective laparoscopic cholecystectomy under general anesthesia were randomly divided into two groups. Inclusion criteria: Age 18-50 years, BMI<30, Stage 1 and 2 ASA; Surgery time less than 2 hours; Absence of systemic disease such as(heart or lung disease and serious liver-Kidney disease); Absence of contraindications to epidural anesthesia (coagulopathies, infection at needle insertion site, the patient's lack of cooperation, absence of consent); Absence of any contraindications to perform Block, Absence of a history of immunosuppressive and corticosteroids drugs; Absence of a history of drug addiction and smoking. Exclusion criteria: Failing to block; Incidence of complications during surgery and laparotomy for any reason; Prolongation of operation (more than 2 hours). Two groups of patients under study, at the beginning of surgery before anesthesia induction fall under TAP BLOCK and Epidural Anesthesia. The success rate of block will be studied in 2 ways: 1. Objective: Injection and deposition of local anesthetic (Marcaine) between the IOM and TAM muscle layers will be determined under ultrasound-guide. 2 Subjective: Check the skin feel of the same area of the block in the epigastric and the umbilicus and the groin about 30 minutes after the block. In both groups before the induction of the patients, 3 blood samples of the patients will be taken, one before the start of induction and the second, 6 hours after extubation and the third, 24 hours after the surgery and in three of them, Blood Sugar, WBC, CRP, Cortisol IL-1 and TNF- α of these patients will be measured and compared. The postoperative pain in both groups of the patients will be measured and compared using the VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092924268N1**

Registration date: **2015-12-07, 1394/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-07, 1394/09/16

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 Research Department

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of TAP Block and Epidural A. on post operative stress response of elective laparoscopic cholecystectomy surgery in shariati hospital -1393

Public title

Comparison of nerve blocks and epidural anesthesia on stress response in patients undergoing general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-50 years; BMI<30; Stage 1 and 2 ASA; Surgery time less than 2 hours; Absence of systemic disease such as (heart or lung disease and serious liver-Kidney disease); Absence of contraindications to epidural anesthesia (coagulopathies, infection at needle insertion site, The patient's lack of cooperation, Absence of consent); Absence of any contraindications to perform Block; Absence of a history of immunosuppressive and corticosteroid drugs; Absence of a history of drug addiction and smoking. Exclusion criteria: Failing to block; Incidence of complications during surgery and laparotomy for any reason; Prolongation of operation (more than 2 hours)

AgeFrom **17 years** old to **49 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **52****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**

Vice Chancellor For Research of Tehran Medical

School, Tehran University of Medical Sciences

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Vice Chancellor For Research of Tehran Medical School, Tehran University of Medical Sciences, Poursina Street, Keshavarz Blvd, Tehran

City

Tehran

Postal code**Approval date**

2015-10-11, 1394/07/19

Ethics committee reference number

IR.TUMS.REC.1394.926

Health conditions studied**1****Description of health condition studied**

General Anesthesia

ICD-10 code

T41.1, T41

ICD-10 code description

Intravenous Anesthetics, Other and Unspecified General Anesthetic, Local Anesthetics

Primary outcomes**1****Description**

Objective success rate of blockage for anesthesia by injection and deposition of sediment material (Marcaine) between the layers of muscle (IOM and TAM)

Timepoint

During of surgery

Method of measurement

Ultrasound sonography

2**Description**

The Subjective Success Rate of Block

Timepoint

30 minute

Method of measurement

Check the skin sensation of the same area of block in the epigastric and umbilical and groin

3**Description**

pain

Timepoint

Immediately, 6, 12, 24 hours after discharge from recovery

Method of measurement

Visualized Analogue Scale

Secondary outcomes

1

Description

Blood Sugar ,WBC , CRP , Cortisol, TNF- α and IL-1 level of serum

Timepoint

Before induction of anesthesia and 6 and 24 hours after extubation of patient

Method of measurement

Blood Exam

Intervention groups

1

Description

At the beginning of surgery before anesthesia induction, TAP BLOCK performed by the Professor of Anesthesiology and with the method of Ultrasound guided Transversus Abdominus plane block with 20 cc Bupivacaine 0.5%

Category

Prevention

2

Description

Initially with 2cc lidocaine 2%, local anesthesia were created then through the number 18 epidural needle inserted into the epidural space then made sure of the correct position of epidural space, 25 cc Bupivacaine 0.25% will be injected.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr Piroozeh Taheri

Street address

Dr Shariati Hospital, Jalal Al Ahmad Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research of Tehran Medical School, Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh, Vice Chancellor For Research of Tehran Medical School, Tehran University of M

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206 Room, First Floor, Medical School, Tehran

University of Medical Sciences, Keshavarz Boulevard, Amir Abad, Tehran

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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 Chancellor For Research of Tehran Medical School, 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

Anesthesiology Department, Dr Shariati Hospital, Tehran University of Medical Sciences, Tehran

Full name of responsible person

Piroozeh Taheri

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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