

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the efficacy of TAP Block on stress responses in candidate patients for elective laparoscopic cholecystectomy surgery in Shariati hospital -1393

Protocol summary

Summary

This study is a clinical trial to compare the two methods of TAP BLOCK nerve blocks with Marcaine and Normal Saline on stress responses of 52 patients undergoing elective laparoscopic cholecystectomy under general anesthesia were randomly divided into two groups. Inclusion criteria: Age of 18-60; 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 in performing Block; Absence of a history of immunosuppressive drugs and corticosteroids; Exclusion criteria for absence of a history of drug addiction and smoking; Failing to block; Incidence of complication during surgery and laparotomy for any reason; Prolongation of operation (more than 2 hours). The patients of two study groups, at the beginning of the surgery before anesthesia induction were put under TAP BLOCK with Marcaine in the intervention group and under normal saline in control group. The success rate of block will be studied in 2 ways: 1. Objective: Injection and deposition of the 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: **IRCT2015100824268N2**

Registration date: **2015-11-19, 1394/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-19, 1394/08/28

Registrant information

Name

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Name of organization / entity

Department of Anesthesia

Country

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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 on stress responses in candidate patients for elective laparoscopic cholecystectomy surgery in Shariati hospital -1393

Public title

Comparison of the effect of Nerve Block with Marcaine and Normal Saline on stress response in patients undergoing general anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-60 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 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 **18 years** old to **60 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)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

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

Street address

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.1394.925

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
Anesthetics, Local Anesthetics

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

pain

Timepoint

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

Method of measurement

Visualized Analogue Scale

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**

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

Timepoint

During of surgery

Method of measurement

Ultrasound sonography

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

Nerve block with TAP Methods with Marcaine in the intervention group

Category

Prevention

2

Description

Nerve block with TAP Methods with Normal Saline in the control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr Farhad Rahimi

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 University, Tehran
University of Medical Sciences

Full name of responsible person

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

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206 Room, First Floor, Medical School, 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 University, 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

Full name of responsible person

Farhad Rahimi

Position

Assistant

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Person responsible for scientific inquiries

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empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty