Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of control of pain in transverse abdominal muscle blocks method with injections of local analgesia effect at the incision site after unilateral inguinal hernia surgery

Protocol summary

Summary

The purpose of this study is postoperative pain management in the patients were randomized to receive transverse abdominis plane block (TAP block) in surgery by injecting local anesthesia. This is a prospective randomized trial in 60 patients, ASA I/ II undergoing unilateral inguinal hernia surgery. Inclusion criteria: Candidates for unilateral inguinal hernia surgery; ASA class I, II Exclusion criteria: Allergic reactions to general anesthesia, Unexpected bleeding; Cardiovascular events; Severe hypertension.The block randomization method is designed to randomize subjects into two groups T and I. All of the patients undergoing general anesthesia. At the end of the surgery group T The Ultrasound-guided Transverse abdominis plane (TAP) block using 20 ml Marcaine 0.25% and adrenaline 1: 200,000 in the surgical area. For group I patients' infiltration of 20 ml 0.25% Marcaine in 1:200000 Adrenalines in the surgery site is done. No routine analgesic is prescribed after the surgery and only if the patients complain of pain and have VAS more than three, 0.1 mg/kg Morphine Sulfate was injected. Patients are visited at 1, 2,4,6,12,18 up to 24 hours after the surgery and the pain score (using VAS 10 score), time of the first request for analgesic, total dose of prescribed analgesic and complications are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506226186N11**
Registration date: **2015-09-08, 1394/06/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-08, 1394/06/17

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-09-25, 1394/07/03

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of control of pain in transverse abdominal muscle blocks method with injections of local analgesia effect at the incision site after unilateral inguinal hernia surgery

Public title

Pain control with transverse abdominal muscle blocks

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidates for unilateral inguinal hernia surgery; ASA class I,II Exclusion criteria: Unexpected bleeding;Cardiovascular events; Severe hypertension

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193833697

Approval date

2015-07-10, 1394/04/19

Ethics committee reference number

IR.GUMS.REC.1394.23

Health conditions studied

1

Description of health condition studied

Femoral hernia (unilateral) NOS

ICD-10 code

K41.9

ICD-10 code description

Unilateral or unspecified femoral hernia, without obstruction or gangrene

Primary outcomes

1

Description

Pain

Timepoint

1, 2, 4, 6, 12, 18 up to 24 hours after surgery

Method of measurement

Visual Analogue Scale (VAS)\Questionnaire

2

Description

Nausea

Timepoint

1, 2, 4, 6, 12, 18 up to 24 hours after surgery

Method of measurement

Yes/No-Questionnaire

3

Description

Drowsiness

Timepoint

1, 2, 4, 6, 12, 18 up to 24 hours after surgery

Method of measurement

Yes/No-Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Tgroup: Transverse abdominis plane (TAP) block with ultrasound using 20 ml Bupivacaine 0.25% and adrenaline 1: 200,000 in the surgical area

Category

Treatment - Drugs

2

Description

I group: infiltration of 20 ml 0.25% Marcain in 1:200000 Adrenalin in the surgery site

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Bahram Naderi Nabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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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 Guilan 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

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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