

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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Person responsible for scientific inquiries

Contact

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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
Street address
Shahid Beheshti Freeway
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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

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Person responsible for updating data

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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