

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison between local and spinal anesthesia in inguinal hernia repair

Protocol summary

Summary

The aim of this randomized clinical trial is to compare the local and spinal Anesthesia complication in inguinal Hernia Repair. A total of 60 patients, meeting eligibility criteria, will be randomly allocated into two equal groups. 30 patients were put into LA group who received local anesthesia, and 30 patients were put into SA group who received Spinal anesthesia. Lichtenstein hernia repair technique will be used for all patients. After establishing routine monitors, 5 cc/kg ringer lactate will be infused for all patients. Local anesthesia will be applied through 10 ml 1.5% lidocaine, 30 ml 0.5% bupivacain and 2 ml 1:200,000 epinephrine mixture. Spinal anesthesia will be performed with 8 mg bupivacain. Anesthesia will be performed on all patients by one anesthesiologist and also, all surgery procedures will be performed by one surgeon. The duration of surgery, type of hernia, urinary retention, hematoma in the area of operation, surgical site infection, pain intensity, analgesic consumption in the first 24 hours after surgery and postoperative length of stay for all patients will be recorded. Patients pain intensity at the 0, 3, 6, 12 and 24 hours after surgery will be recorded by Visual Analogue Scale. Also, patients will have a physical exam at the end of the first week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403316803N6**

Registration date: **2014-04-09, 1393/01/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-09, 1393/01/20

Registrant information

Name

Abolfazl Firouzian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 15 1222 6655

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between local and spinal anesthesia in inguinal hernia repair

Public title

Inguinal hernia repair with local anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed written consent; Age between 18 - 70 years; Elective inguinal hernia. Exclusion criteria: Recurrent hernia; Incarcerated hernia; Hydrocele; Femoral hernia; Bilateral hernia; Pregnancy; Sensitivity to local anesthetic drugs; Diabetes mellitus;

Coagulopathy disorder; substance abuse.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

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 Mazandaran University of
Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem
Square.

City

Sari

Postal code

4817844718

Approval date

2013-05-17, 1392/02/27

Ethics committee reference number

91-110

Health conditions studied

1

Description of health condition studied

Local anesthesia

ICD-10 code

t88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description

Intensity of postoperative pain

Timepoint

At the end of surgery and 3, 6, 12 and 24 hours after
surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Duration of surgery

Timepoint

During surgery

Method of measurement

Questionnaire

2

Description

Urinary retention

Timepoint

After surgery

Method of measurement

Questionnaire

3

Description

Hematoma in the area of operation

Timepoint

After surgery and at the end of the first week

Method of measurement

Questionnaire

4

Description

Surgical site infection

Timepoint

At the end of the first week

Method of measurement

Questionnaire

5

Description

postoperative length of stay

Timepoint

After surgery

Method of measurement

Questionnaire

6

Description

Analgesic consumption in the first 24 hours after surgery

Timepoint

In the first 24 hours after surgery

Method of measurement

Questionnaire

Intervention groups**1****Description**

For inguinal hernia repair in control group, spinal anesthesia will be performed with 8 mg bupivacain.

Category

Treatment - Other

2**Description**

For inguinal hernia repair in intervention group, local anesthesia will be applied through 10 ml 1.5% lidocaine, 30 ml 0.5% bupivacain and 2 ml 1:200,000 epinephrine mixture.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini Hospital

Full name of responsible person

Abolfazl Firouzian MD, Assistant Professor

Street address

Emam Khomeini Hospital, Amir mazandarani Ave.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran University of Medical Sciences, Moallem Square.

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Sari

Grant name

10506

Grant code / Reference number

1512

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Sadegh Zamani Ranani

Position

General Surgeon, Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Abolfazl Firouzian MD

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work**Street address**

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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