

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison effects of Bupivacaine and Lidocaine - Bupivacaine on hemodynamic parameters in patients with hip fracture surgery

Protocol summary

Summary

This study compared the effects of Bupivacaine and Lidocaine - Bupivacaine on hemodynamic parameters in patients with hip fracture surgery. Inclusion criteria: 60-70 years old patients with ASA I-III that candidate for hip surgery. Contraindications of spinal anesthesia or uncontrolled Hypertension, ischemic heart disease, heart failure, recent myocardial infarction (MI) or active ischemia in Electrocardiography (ECG) do not enter the study. Patients are divided randomly into 2 groups, A (10 mg Bupivacaine 0.5%) and B (5 mg Bupivacaine 0.5% + 50 mg Lidocain 5%), 0.2 mg Epinephrine is added to both groups. Then blood pressure, heart rate, sensory and motor blocks before spinal anesthesia and immediately after spinal anesthesia are checked every 5 minutes until 30 minutes. Numbers of hypotension, total dose of vasopressors and nausea and vomiting are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102713456N2**
Registration date: **2014-12-07, 1393/09/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name

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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

2014-11-22, 1393/09/01

Expected recruitment end date

2016-06-23, 1395/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of Bupivacaine and Lidocaine - Bupivacaine on hemodynamic parameters in patients with hip fracture surgery

Public title

Hemodynamic control on spinal patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : 60-70 years old patients with ASA I-III that candidate for hip surgery. contraindications of spinal anesthesia or uncontrolled Hypertension, ischemic heart disease, heart failure, recent myocardial infarction (MI) or active ischemia in Electrocardiography(ECG) do not enter the study

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 133

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Science

Street address

Namjoo Street

City

Rasht

Postal code

4193893345

Approval date

2014-08-26, 1393/06/04

Ethics committee reference number

1930231617

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

Regional anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

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

Systolic blood pressure less than 90 mmHg or reduced mean arterial pressure more than 25%

Timepoint

Immediately after the injection then every 5 minutes up to 30 minutes

Method of measurement

mmHg by Saadat monitoring system

2**Description**

Heart Rate

Timepoint

Immediately after the injection then every 5 minutes upto 30 minutes

Method of measurement

Beats per minute (bpm) by Saadat monitoring system

Secondary outcomes**1****Description**

Nausea

Timepoint

Immediately after the injection then every 5 minutes up to 30 minutes

Method of measurement

Nausea score (0-4)

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

Intervention 1) 1 milligram Bupivacaine 0.5%

Category

Treatment - Drugs

2**Description**

Intervention 2) Five milligram Bupivacaine 0.5% with 50 milligram Lidocaine 5%

Category

Treatment - Drugs

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

Poursina Hospital

Full name of responsible person

Abbas Sedighinejad

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Parastar Street

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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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Shahid beheshti Highway

City

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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**

Guilan University of Medical Sciences

Full name of responsible person

Abbas Sedighinejad

Position

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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