Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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Abbas Sedighinejad

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 redused mean artherial 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
Street address
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
Street address
Shahid beheshti Highway
City
Rasht
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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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