Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of general anesthesia with sevoflurane and low-dose spinal anesthesia with 5% lidocaine on hemodynamic signals in patients undergoing hip fracture

Protocol summary

Summary

This is a randomized clinical trial study, to evaluate and compare the two methods of general anesthesia with Sevoflurane, and spinal anesthesia with low-dose of Lidocaine 5% in patients that undergoing hip fracture surgery.Sample size for this study is100 patients. Patients randomized with Block Randomization in two groups, General anesthesia (GA) and Spinal anesthesia(SA).In General anesthesia (GA) group, after Oxygenation mask , induction with Fentanyl, followed by Propofol until loss of consciousness, then Atracorium administered.Anesthesia maintening is Sevoflurane in Oxygen and Nitrous Oxide in the spinal group, Lidocaine 5%(1.5 cc) inject and for sedation 1 mg Midazolame and 50 microgram Fentanyl. Vital sign such as Heart rate, systolic and diastolic pressure measure every 15 minutes and in the end of surgery bleeding volume is recorded. Inclusion criteria: patients older than 30 years old with class ASA 1-3, who schedule for elective operative fixation of fractured hip.Exclusion criteria include: dementia ; congnitive dysfunction; history of Opioid or psychotic drug use.Patients with hupersensitivity to anesthetic drugs; Sever liver and kidney Diseases; sever bleeding; hypotention needed to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308316280N4**
Registration date: **2014-03-15, 1392/12/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-03-15, 1392/12/24

Registrant information

Name
Mohammad Haghighi
Name of organization / entity
Guilan University of Medical Sciences
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Iran (Islamic Republic of)
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mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-03-16, 1392/12/25

Expected recruitment end date

2014-09-16, 1393/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of general anesthesia with sevoflurane and low-dose spinal anesthesia with 5% lidocaine on hemodynamic signals in patients undergoing hip fracture

Public title

Hemodynamic effects of general and spinal anesthesia for hip fracture surgery

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:aged over 30; ASA class 1-3 with hip

fracture fixation surgery Exclusion criteria: Dementia or cognitive dysfunctions and no history of opioid or psychotic drugs use; Patients with hypersensitivity to anesthetic drugs; sever liver,kidney and pulmonary diseases; sever bleeding; hypo-tension that requiring treatment

Age
From **30 years** old to **100 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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 GuilanUniversity of Medical Sciences

Street address
Shahid Beheshti freeway

City
Rasht

Postal code
4193893345

Approval date
2013-12-07, 1392/09/16

Ethics committee reference number
1920341306

Health conditions studied

1

Description of health condition studied
Hip fracture

ICD-10 code
S72.2

ICD-10 code description
Subtrochanteric fracture

Primary outcomes

1

Description
Bleeding

Timepoint
End of surgery

Method of measurement
ml/ numbers of bloody Gauze

2

Description
Blood Pressure

Timepoint
0-15-30-45-60 times and every 15 minutes during the recovery up to 24 hours

Method of measurement
mmHg/ saadat company

3

Description
Heart Rate

Timepoint
0-15-30-45-60 times and every 15 minutes during the recovery up to 24 hours

Method of measurement
The number in the Minutes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: Spinal Anesthesia with Low-dose lidocaine 5%

Category
Treatment - Drugs

2

Description
Intervention 2: General anesthesia with sevoflurane

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina Hospital

Full name of responsible person
Mohammad Haghighi

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

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Anesthesiologist/associated Professor

Other areas of specialty/work

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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