

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 is 100 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 Atracurium administered. Anesthesia maintaining is Sevoflurane in Oxygen and Nitrous Oxide in the spinal group, Lidocaine 5% (1.5 cc) inject and for sedation 1 mg Midazolam 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; cognitive dysfunction; history of Opioid or psychotic drug use. Patients with hypersensitivity to anesthetic drugs; severe liver and kidney diseases; severe bleeding; hypotension 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

Country

Iran (Islamic Republic of)

Phone

+98 13 3211 1319

Email address

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
City
Rasht

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

Street address

Poursina Hospital

City

Rasht

Postal code

4193713194

Phone

+98 13 1321 0434

Fax

+98 13 1323 9842

Email

mohaghighi@gums.ac.ir, arcguilan1392@gmail.com

Web page address

www.gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Anesthesiologists/associated professor

Other areas of specialty/work

Street address

Poursina hospital

City

Rasht

Postal code

4193713194

Phone

+98 13 1321 0434

Fax

+98 13 1324 5140

Email

mohaghighi@gums.ac.ir, arcguilan1392@gmail.com

Web page address

www.gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Hedieh Nemati

Position

Bachelor's Degree/ Medical laboratory Sciences
Technician

Other areas of specialty/work

Street address

Poursina Hospital

City

Rasht

Postal code

4193713194

Phone

+98 13 1321 0434

Fax

+98 13 1324 5132

Email

nematihedieh@gmail.com, arcguilan1392@gmail.com

Web page address

www.gums.ac.ir

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