Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of hypobaric unilateral spinal anesthesia versus general anesthesia on heart rate, blood pressure change and mortality in hip fracture surgery

Protocol summary

Study aim
To determine the comparative effect of unilateral spinal anesthesia versus general anesthesia on hemodynamics and mortality in hip fracture surgery in the elderly.

Design
Controlled clinical trial, with parallel groups, phase 3 on 60 patients.

Settings and conduct
This study will be conducted as a clinical trial on patients over 60 years of age with hip fracture referred to Shahid Rajaee Hospital in Qazvin. In the intervention group, patients will undergo unilateral spinal anesthesia with hypobaric solution injection including ropivacaine and sufentanil in the subarachnoid space. In the control group, patients will undergo general anesthesia with standard drugs including propofol, midazolam, sufentanil, atracurium, and isoflurane. In both groups, mean arterial blood pressure (MAP) and heart rate will be recorded every three minutes before, during, and after the operation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People over 60 years of age referring to Shahid Rajaee Hospital in Qazvin who are undergoing orthopedic surgery due to a hip fracture. Exclusion criteria: multiple trauma (multiple injuries or damage to other organs), increased intracranial pressure (high ICP), emergency surgery or urgent need for anesthesia, spinal injection site infection, coagulation disorders or high INR, history of stroke (CVA) or myocardial infarction (MI) within the last three months, patients in shock.

Intervention groups
Intervention group: Anesthesia is performed by intra-subarachnoid injection of hypobaric solution containing ropivacaine and sufentanil. Control group: Patients are placed under general anesthesia with standard drugs including propofol, midazolam, sufentanil, atracurium and isoflurane.

Main outcome variables
Incidence of severe intraoperative hypotension, intraoperative norepinephrine and ephedrine intake, seven-day postoperative mortality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250809066791N1**
Registration date: **2025-11-04, 1404/08/13**
Registration timing: **prospective**

Last update: **2025-11-04, 1404/08/13**
Update count: **0**

Registration date
2025-11-04, 1404/08/13

Registrant information
Name
Tarokh Rajabinezhad
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-04-21, 1405/02/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hypobaric unilateral spinal anesthesia versus general anesthesia on heart rate, blood pressure change and mortality in hip fracture surgery

Public title

Comparison of hypobaric unilateral spinal anesthesia versus general anesthesia on heart rate, blood pressure change and mortality in hip fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People over 60 years of age who visit Shahid Rajaee Hospital in Qazvin and undergo orthopedic surgery due to a hip fracture

Exclusion criteria:

Allergy to ropivacaine Multiple trauma

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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 Qazvin University of Medical Sciences

Street address

Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd

City

Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2025-11-02, 1404/08/11

Ethics committee reference number

IR.QUMS.REC.1404.276

Health conditions studied

1

Description of health condition studied

Hip fracture surgery

ICD-10 code

S72.0

ICD-10 code description

Fracture of head and neck of femur

Primary outcomes

1

Description

Severe hypotension during surgery

Timepoint

From the start of anesthesia to the end of the surgery

Method of measurement

Non-invasive blood pressure measurement with standard monitoring every three minutes

2

Description

Intraoperative norepinephrine intake

Timepoint

From the start of anesthesia or numbing to the end of the surgery

Method of measurement

Total dose recorded on the anesthesia sheet

3

Description

Amount of ephedrine taken during surgery

Timepoint

From the start of anesthesia or numbing to the end of the surgery

Method of measurement

Total dose recorded on the anesthesia sheet

4

Description

Seven-day postoperative mortality

Timepoint

From the end of surgery to seven days later

Method of measurement

Clinical follow-up and hospital record review

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Unilateral Spinal Anesthesia with Ropivacaine and Sufentanil: In this group, patients undergo Unilateral Spinal Anesthesia (ULSA). After injecting 500 cc of normal saline, the patient is placed in a sitting position. The hypobaric anesthetic solution is prepared with the following ingredients: 0.5% Ropivacaine, 2 ml (10 mg) of Sufentanil, 1 ml (5 µg) of distilled water, 1 ml. A total of 4 cc of the prepared solution is injected into the subarachnoid space L4–L5 (or a higher or lower space) with a 23 G needle. After injection, the patient is placed in a lateral position on the non-involved side (fracture area upwards) for 5 minutes to limit the spread of the drug to that side. In case of mild pain during the procedure (NRS <4), an opioid infusion is used. If the patient's pain is not controlled, general anesthesia is performed and the patient is excluded from the study. Monitoring of mean arterial blood pressure (MAP) and heart rate is performed every 3 minutes, as in the control group, and in case of hypotension, treatment with ephedrine and, if necessary, norepinephrine is performed.

Category

Treatment - Drugs

2

Description

Control group: General anesthesia with isoflurane and standard induction drugs: In this group, patients are put under general anesthesia. After injecting 500 cc of normal saline and premedication with midazolam at a dose of 0.02 mg/kg, sufentanil at a dose of 0.2 µg/kg, propofol at a dose of 1 mg/kg, and atracurium at a dose of 0.5 mg/kg, anesthesia is used to induce anesthesia. After ensuring proper airway conditions and performing endotracheal intubation, the patient's anesthesia is maintained with isoflurane and oxygen/medical air based on the patient's hemodynamic status. During the procedure, mean arterial blood pressure (MAP) and heart rate are monitored every 3 minutes. In case of hypotension, a bolus of ephedrine 5 to 10 mg is first injected and repeated if necessary up to a maximum of 20 mg. If hypotension persists, norepinephrine infusion is initiated at a dose of 5–10 µg/min. At the end of the procedure, the patient is monitored and data are recorded for hemodynamic parameters during recovery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei hospital

Full name of responsible person
Tarokh Rajabinezhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Qazvin University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Tarokh Rajabinezhad

Position
resident

Latest degree
Medical doctor

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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available