

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of spinal anesthesia and general anesthesia on postoperative pain and patient discharge time in open femur fractured surgeries

Protocol summary

Summary

Postoperative pain can cause patient restlessness, cardiopulmonary complications, reduction of immune system function, hyperglycemia, urinary retention and ileus. Postoperative analgesia causes patient comfort and reduces morbidity, discharge time and hospital cost. In this single blind clinical trial 60 male or female with 18-65 years old that Scheduled for open reduction and internal fixation of femur fracture (neck, subtrochanteric and intertrochanteric) randomly assigne in spinal or general anesthesia after justification and obtaining consent. In intervention group 2ml of 0.5% hyperbaric bupivacaine will be injected in subarachnoid space through L3-L4 space sand block level up to T10 will be produced. In control group (general anesthesia)) premedication will be fentanyl (1µg/kg) and midazolam (0.05mg/kg), induction of anesthesia thiopental Na (5mg/kg) and Atracurium (0.4mg/kg) for muscle relaxation, maintenance of anesthesia with administration of 1.5%> isoflurane and equal proportions of oxygen and Nitrous oxide. Measurable outcomes after operation are 1- postoperative pain that at the end of recovery and then every 4 hours up to 24 hours will be assessed according to 0-10 numerical pain rating scale. 2- total injected pethidine dose in the first 24 hours and 3-end of operation to discharge time interval in hour also will be assessed. data analysis will be performed with SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052412123N5**

Registration date: **2016-06-06, 1395/03/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-06, 1395/03/17

Registrant information

Name

Javad Nourian

Name of organization / entity

Imam Hossein Hospital, Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 27 3334 2001

Email address

javadnourian@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research, Shahroud University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of spinal anesthesia and general anesthesia on postoperative pain and patient discharge time in open femur fractured surgeries

Public title

Postoperative pain and discharge time after open reduction of femur fracture under spinal anesthesia and

comparison with general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: male and female with 18-65 years old, open reduction and internal fixation of femur fractures(neck, subtrochanteric and intertrochanteric) Exclusion: Patient's refusal, drug abuse, history of anticonvulsive or antidepressive medication, surgery or anesthesia complications

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Deputy of research, Shahroud University of Medical Sciences

Street address

Deputy of research, Shahroud University of Medical Sciences, 7th of Tir square

City

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Postal code

3614773955

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

930.18

Health conditions studied

1

Description of health condition studied

Fracture of neck of femur

ICD-10 code

S72.1

ICD-10 code description

Pertrochanteric, Intertrochanteric & Terochantric fracture

Primary outcomes

1

Description

Postoperative pain

Timepoint

at the end of recovery and then every 4 hours up to 24 hours(before pethidine injection)

Method of measurement

0-10 Numerical pain rating scale(NPS)

2

Description

Discharge time

Timepoint

End of surgery to discharge from hospital

Method of measurement

hour

Secondary outcomes

1

Description

Total dose of pethidine

Timepoint

dose and time of each pethidine injection in recovery and in orthopedia ward in first postoperative day

Method of measurement

Milligram in first postoperative day

Intervention groups

1

Description

Control group: or general anesthesia group, premedication with 1.5 microgram/kg and midazolam 0.05 microgram/kg, Induction with thiopental Na 5 mg/kg and muscle relaxation with 0.4 mg/kg atracurium. Maintenance of anesthesia performs with equal proportion of O2/N2O and 1.5% isoflurane. Depth of anesthesia and muscle relaxation assessment will be controled

Category

Treatment - Drugs

2

Description

Intervention group: after justification and consent in a sterile situation a 25 gauge spinal needle will be inserted in subarachnoid space from L3-L4 intervertebral space. After injection of 2ml of 0.5% hyperbaric bupivacaine,

supine position with 20 degree head and chest up position will be selected until the block level reaches to umbilical line(T10).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Imam hossein hospital

Full name of responsible person

Dr Javad Nourian

Street address

Imam Hossein Hospital, operation room, End of
Ayatollah Towhidi avenue

City

Shahroud

Full name of responsible person

Javad Nourian MD

Position

Assistant professor of anesthesiology, department of
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Other areas of specialty/work

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research, Shahroud University of Medical
Sciences

Full name of responsible person

Mohammad hasan Emamian

Street address

Deputy of research, Shahroud University of Medical
Sciences, 7th of Tir square

City

Shahroud

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Deputy of research, Shahroud 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

Imam Hossein Hospital, Shahroud University of
Medical Sciences, Shahroud, Iran

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Imam Hossein Hospital, Shahroud University of
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Full name of responsible person

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Position

Assistant professor of anesthesiology, department of
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Person responsible for updating data

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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