

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of two methods of midline interlaminar and parasagittal interlaminar epidural anesthesia in patients undergoing orthopedic surgery in the lower extremities

Protocol summary

Summary

Objectives: This study is aimed to comparison of two methods of midline interlaminar and parasagittal interlaminar epidural anesthesia in patients undergoing orthopedic surgery in the lower extremities. Design: Double blind randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: forty patients, with patient candidate for tibial shaft fracture orthopedic surgery; Tibial fracture, which passed 120-90 minute of it; Age more than 18 yr; ASA Class I- II undergoing orthopedic surgery in the lower extremities in Akhtar Hospital were included. Patients were randomized into two groups of midline interlaminar and parasagittal interlaminar 20 patients . Intervention: Intervention group , patients received parasagittal interlaminar and control group, midline interlaminar . Main outcome measures (variables): Sensory block; Motor block; Duration of sensory block; Duration of motor block, Blood pressure; Heart rate; Bradycardia ; Hypotension. Secondary outcome measures (variables): Nausea; Vomiting; Headache; Bleeding; Urinary retention. The type of method are coded by individual not aware of the research process.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041615515N2**

Registration date: **2017-05-02, 1396/02/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-02, 1396/02/12

Registrant information

Name

Masoud Hashemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences and Health Services

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of midline interlaminar and parasagittal interlaminar epidural anesthesia in patients undergoing orthopedic surgery in the lower extremities

Public title

Comparison of two methods midline and lateral of epidural anesthesia in patients undergoing orthopedic surgery in the lower extremities

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient candidate for tibial shaft fracture orthopedic surgery; Tibial fracture, which passed 120-90 minute of it; Age more than 18 yr; ASA Class I- II; Signed written informed consent to participate in the study. Exclusion criteria: Pregnant women; Sepsis; Emergency surgeries; Infection at the site of injection; Coagulopathy or other bleeding diathesis; Spinal deformity; Diabetes; Systemic disease and neuropathy; History of surgery on the lumbar spine; Facet joint arthropathy; Cauda equina syndrome and other unstable neurologic deficits; Allergic to contrast or lidocaine.

Age

From **19 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Shahid Beheshti University of Medical Sciences and Health Services

Street address

Tabnak St.

City

Tehran

Postal code

Approval date

2015-05-17, 1394/02/27

Ethics committee reference number

SBMU.REC.1394.22

Health conditions studied

1

Description of health condition studied

Tibial shaft fracture

ICD-10 code

S82.109

ICD-10 code description

Unspecified fracture of upper end of unspecified tibia

Primary outcomes

1

Description

Blood pressure

Timepoint

Before and after anesthesia to end of surgery

Method of measurement

mmHg

2

Description

Heart rate

Timepoint

Before and after anesthesia to end of surgery

Method of measurement

bpm

3

Description

Sensory block

Timepoint

After anesthesia to exit of recovery

Method of measurement

Pinprick test

4

Description

Motor Block

Timepoint

After anesthesia to exit of recovery

Method of measurement

Bromage score

5

Description

Duration of sensory block

Timepoint

After anesthesia

Method of measurement

Minute

6

Description

Duration of motor block

Timepoint

After anesthesia

Method of measurement

Minute

7

Description

Bradycardia

Timepoint

After anesthesia to end of surgery

Method of measurement

bpm

8

Description

Hypotension

Timepoint

After anesthesia to end of surgery

Method of measurement

mmHg

Secondary outcomes

1

Description

Nausea

Timepoint

After entering the recovery

Method of measurement

Ask the patient

2

Description

Vomiting

Timepoint

After entering the recovery

Method of measurement

Ask the patient

3

Description

Headache

Timepoint

After entering the recovery

Method of measurement

Ask the patient

4

Description

Bleeding

Timepoint

After entering the recovery

Method of measurement

The amount collected in the drain

5

Description

Urinary retention

Timepoint

After entering the recovery

Method of measurement

Urinary catheter

Intervention groups

1

Description

Intervention group: Patients received parasagittal interlaminar of epidural anesthesia.

Category

Prevention

2

Description

Control group: Patients received midline interlaminar of epidural anesthesia.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Masoud Hashemi MD

Street address

Elahiye St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person

Seyed Ali Ziai P.H.D

Street address

Parvaneh St., Yaman St., Shahid Chamran Expressway

City

Tehran

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, Shahid Beheshti University of Medical Sciences and Health Services

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

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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