

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effectiveness of combined sciatic -femoral nerve blocks together with lateral femoral cutaneous nerve block on thigh tourniquet pain with spinal anesthesia in foot and ankle orthopedic surgery patients

Protocol summary

Study aim

The effect of combined block of lateral femoral cutaneous nerve and femoral nerve on thigh tourniquet pain during unilateral foot or ankle orthopedic surgery.

Design

A two-arm parallel, randomized controlled clinical trial with concealed blinded randomization sequence and blinded outcome assessment.

Settings and conduct

Sixty patients in Akhtar Hospital affiliated to Shahid Beheshti University of Medical Sciences are randomly enrolled into two equal groups after obtaining informed consent. When a satisfactory level of block is achieved, a thigh tourniquet is inflated in the proximal part of the thigh. The tourniquet pain is assessed by a blinded observer immediately after inflation and then every 5 min with a 5-point verbal rating scale (VRS). If the patient complains of pain or VRS was >1 , bolus doses of intravenous fentanyl or ketamine are given alternatively.

Participants/Inclusion and exclusion criteria

ASA I-II patients are included. Patients with allergy to local anesthetics, coagulation disorders, opium addiction, infection at the block site, previous femoral or popliteal bypass surgery, BMI ≥ 30 , sickle cell anemia, and lack of cooperation are excluded.

Intervention groups

In the Spinal group, 3 ml of 0.5% hyperbaric bupivacaine is injected intrathecally. In the Peripheral nerve block group, popliteal, femoral nerve (FN), and lateral femoral cutaneous nerve (LFCN) block is performed under the guidance of ultrasound. 20 ml of 1.5% lidocaine with epinephrine 1:200000 + bicarbonate is administered for popliteal block, 15 ml and 5 ml of the same solution for FN and LFCN, respectively. After 20 minutes, sensory block is assessed by the pinprick testing and the motor block by the modified Bromage scale by a blinded

observer.

Main outcome variables

Intraoperative tourniquet pain; block performance time; surgical anesthetic effect time; total doses of intraoperative analgesics.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131108015322N3**

Registration date: **2020-05-25, 1399/03/05**

Registration timing: **retrospective**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Shideh Dabir

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of combined sciatic -femoral nerve blocks together with lateral femoral cutaneous nerve block on thigh tourniquet pain with spinal anesthesia in foot and ankle orthopedic surgery patients

Public title

"Effect of combined sciatic -femoral nerve blocks and lateral femoral cutaneous nerve on thigh tourniquet pain in foot and ankle orthopedic surgery"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA class I,II Age 18-70 years Unilateral foot and ankle orthopedic surgery

Exclusion criteria:

ASA class $\geq$ III Allergy to local anesthetics Coagulation disorders opium addiction Uncooperative patient Infection at nerve block site Vascular grafting of femoral or popliteal vessels BMI $\geq$ 30 Sick cell anemia Extensive and traumatic surgery of tibia and fibula Tourniquet inflation time less than 60 minutes Patient refusal

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants are randomly assigned to 1 of 2 groups following simple randomization by using a random numbers table . The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes. After acceptance of the eligible patient and in the operating room, the numbered envelope is opened by an investigator with no clinical involvement in the trial. Randomization and assignment of patients is done by a person not involved in the study. The person who measures the outcome in two groups is also kept blinded.

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**

Research Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Building No. 2, 6th floor, Office of Research Affairs, Shahid Chamran Highway, Yemen St., Arabi St., next to Taleghani Hospital

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Tehran

Postal code

1983963113

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.SBMU.MSP.REC.1398.058

Health conditions studied**1****Description of health condition studied**

Treatment of thigh tourniquet- related acute pain during lower limb surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Intraoperative severity of tourniquet pain

Timepoint

Immediately after tourniquet inflation, and then every 5 min until the end of surgery

Method of measurement

Tourniquet pain intensity is evaluated by using a 5-point verbal rating scale (VRS) (0 =no pain, 1= mild pain, 2=moderate pain, 3= severe pain, 4=unbearable pain).

Secondary outcomes**1****Description**

Time taken to perform the block

Timepoint

The time taken from the beginning to the end of local anesthetic injection

Method of measurement

The interval (minutes) between the beginning to the end of local anesthetic injection

2

Description

Anesthetic effect time

Timepoint

Time required from the end of local anesthetic injection to achieve adequate anesthesia

Method of measurement

The interval (minutes) between the end of local anesthetic injection and block success required for surgical anesthesia

3

Description

Intraoperative total doses of fentanyl and ketamin

Timepoint

During operation

Method of measurement

Boluses of intravenous fentanyl (μg) or ketamine (mg) given during surgery are recorded and for each drug, the total dose was calculated.

Intervention groups

1

Description

Control group: In the patients in the control group, the standard method of spinal anesthesia is performed in the lateral position. 3 ml of 0.5% hyperbaric bupivacaine is injected intrathecally using a 25G Quincke spinal needle. Then the patients are placed in the supine position.

Category

Treatment - Other

2

Description

Intervention group: In this group, blockade of popliteal, femoral nerve (FN), and lateral femoral cutaneous nerve (LFCN) block are performed under the guidance of ultrasound (SonoSite S-Nerve, Bothell, WA, USA) using a 6-13 MHz linear transducer and a 22G-bevel 30°, 85 mm block needle (Visioplex®, Vygon, Ecouen, France). In the lateral position, 20 ml of 1.5% lidocaine with epinephrine 1:200000 + bicarbonate is administered for popliteal block . 15 ml and 5 ml of the same solution is injected for block of the FN and LFCN, respectively in the supine position.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Faramarz Mosaffa

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, PhD

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shideh dabir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address<http://taleghani.sbm.ac.ir/>**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**

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/documentStudy Protocol: The whole research protocol are to be
shared.**When the data will become available and for how****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shideh Dabir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Taleghani Hospital, Arabi St., Yemen St., Velenjak**City**

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long

There is no further information.

To whom data/document is available

There is no further information.

Under which criteria data/document could be used

There is no further information.

From where data/document is obtainable

There is no further information.

What processes are involved for a request to access data/document

There is no further information.

Comments