Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness of fascia iliaca block plus popliteal block on thigh tourniquet pain in below- knee orthopedic surgery compared with spinal anesthesia

Protocol summary

Study aim

To determine the effectiveness of fascia iliaca block on thigh tourniquet pain during unilateral below-knee orthopedic surgeries

Design

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

Settings and conduct

72 patients are recruited from Akhtar hospital affiliated to Shahid Beheshti University of Medical Sciences after obtaining informed consent. They are randomly divided into two equal groups of spinal anesthesia and fascia iliaca block by a blinded investigator. When a satisfactory block is achieved, a pneumatic thigh tourniquet is inflated in the proximal part of the thigh. The tourniquet pain is assessed by a blinded observer immediately after tourniquet inflation and then every 5 min until the end of surgery with a 5-point verbal rating scale (VRS). If the patient complains of pain or VRS >1, bolus doses of intravenous fentanyl or ketamine are given alternatively. If inadequate, general anesthesia is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A$A 1 or 2 patients, aged 14 to 80 years, scheduled for unilateral below-knee orthopedic surgery using a pneumatic thigh tourniquet. Exclusion criteria: Patients with allergy to local anesthetics, coagulation disorders, opium addiction, infection at the block site, previous femoral or popliteal bypass surgery, BMI more than 30, sickle cell anemia, tourniquet inflation time less than 60 minutes, and lack of cooperation.

Intervention groups

In the patients in the control group, the standard method of spinal anesthesia is performed. In the Intervention group, fascia iliaca and popliteal blockades are performed under the guidance of ultrasound

Main outcome variables

Severity of tourniquet pain during surgery; time to perform the block; anesthetic effect time; total doses of analgesics given intraoperatively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131108015322N4**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Shideh Dabir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2595

Email address

sdabir@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-12, 1398/02/22

Expected recruitment end date

2020-03-16, 1398/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of fascia iliaca block plus popliteal block on thigh tourniquet pain in below-knee orthopedic surgery compared with spinal anesthesia

Public title

Effect of fascia iliaca block on thigh tourniquet pain in orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA class1 and 2 unilateral surgery

Exclusion criteria:

Allergy to local anesthetics Age> 80 yrs Coagulation disorders Opium addiction Infection at the block site Previous femoral or popliteal bypass surgery BMI ≥30 Sickle cell anemia Tourniquet inflation time less than 60 minutes Uncooperative patients

Age

From **14 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

We used a simple random sampling method using a table of random numbers to generate a random sequence of patients. even numbers were considered for the peripheral nerve block group and odd numbers for the spinal anesthesia group. The researcher then touches one of the numbers in the table of random numbers and moves in the right direction of the table, recording the numbers and assigning them to two groups. Each random sequence is recorded on a card. When the eligible participants enter the study, the cards are selected in order of their sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

Randomization, assignment of patients in each group, and random selection of envelopes is done by an investigator with no involvement in the trial. The person who measures the outcomes is also kept blinded.

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, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.Sbmu.Retech.Rec.1397.1370

Health conditions studied

1

Description of health condition studied

management of acute tourniquet pain during below-knee surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of tourniquet pain during surgery

Timepoint

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

Method of measurement

Using a 5-point verbal rating scale (VRS) consisting of; 0 =no pain, 1= mild pain, 2=moderate pain, 3= severe pain, 4=unbearable pain.

Secondary outcomes

1

Description

Block performance time

Timepoint

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

Method of measurement

The interval between the beginning to the end of local anesthetic injection in minutes.

2

Description

Anesthetic effect time

Timepoint

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

Method of measurement

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

3

Description

The total doses of fentanyl and ketamine administered.

Timepoint

During surgery

Method of measurement

Intravenous boluses of fentanyl (µg) or ketamine (mg) given during surgery are recorded and the total dose given for each drug is calculated.

Intervention groups

1

Description

Control group: In the patients in the control group, the method of spinal anesthesia is performed. In these patients, 15 mg of 0.5% hyperbaric bupivacaine is injected intrathecally using a 25G Quincke spinal needle.

Category

Treatment - Other

2

Description

Intervention group: In this group, fascia iliaca and popliteal blockades are performed under the guidance of ultrasound (SonoSite S-Nerve, Bothell, WA, USA) using a 6-13 MHz linear transducer. For the popliteal block, 20 ml of lidocaine 1.5% + epinephrine 1:200000 is administered. For fascia iliaca block, 30 ml of the same solution is injected just below the fascia iliaca.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person

Faramarz Mosaffa

Street address

Department of Anesthesiology, Akhtar Hospital, Shariati Ave., Pole- Rumi St., Sharifimanesh St., Azar dead end

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2664 0307

Email

faramarzmosaffa@yahoo.com

Web page address

http://amc.sbmu.ac.ir/#

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, phD

Street address

Building No. 2, 5th floor, Office in Research Affairs, shahid Beheshti University of Medical sciences, Shahid Chamran Highway, Yemen St., Arabi St., next to Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Fax

+98 21 2243 9981

Email

Mpajouhesh@sbmu.ac.ir

Web page address

http://retech.sbmu.ac.ir/index.jsp?fkeyid=&siteid=24&pageid=2554

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
Street address
Anesthesiology and Critical care Department, Taleghani Hospital, Arabi St., Yemen St., Velenjak
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2595
Email
shdabir@yahoo.com
Web page address
http://taleghani.sbmu.ac.ir/

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
Street address
Anesthesiology and Critical care Department, Taleghani Hospital, Arabi St., Yemen St., Velenjak
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2595
Email
shdabir@yahoo.com
Web page address
http://taleghani.sbmu.ac.ir/

Person responsible for updating data

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
Street address
Anesthesiology and Critical care Department, Taleghani Hospital, Arabi St., Yemen St., Velenjak
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2595
Email
shdabir@yahoo.com
Web page address
http://taleghani.sbmu.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available