Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of ultrasound guided femoropopliteal block versus spinal anesthesia for ankle surgery

Protocol summary

Study aim
To compare the sensory, motor, block duration and added analgesia requirements between ultrasound guided femoropopliteal block and spinal anesthesia in patients with malleolar fractures of the ankle.

Design
A randomized control trial was carried out at the Department of anesthesiology. A pilot study was carried out before the start of the trial with 15 participants in each group, one to receive spinal anesthesia and the other to be administered femoropopliteal block under ultrasound guidance for malleolar fracture of the ankle.

Settings and conduct
The method of randomization was non-probability consecutive sampling by lottery method.

Participants/Inclusion and exclusion criteria
Included all ASA-I and II male and female patients between ages 25-55 years. Excluded patients with major cardiac or respiratory disease, patients with failed spinal or femoropopliteal block after three unsuccessful attempts, patients allergic to local anesthetic including bupivacaine, lignocaine and steroids including dexamethasone, patients with malignancy or malignant disease, pregnant females and patients unwilling to be included in the study.

Intervention groups
The trial randomized all patients as per the inclusion criteria furnished. The patients were divided into the spinal group and the femoropopliteal block group. Once the patients were divided into the two groups, an informed written consent was taken, and patients in both groups were explained in detail about the procedure and possible complications. Standard monitoring including non-invasive blood pressure, heart rate, capnography and ECG were attached to participants in both groups.

Main outcome variables
Duration of surgery. Mean time to onset of sensory block. Mean time to onset of motor block. Mean time to first dose rescue analgesia. Mean time of analgesia given in HDU. Mean HDU stay. Mean patient satisfaction score for pain releif.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231211060337N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date
2024-01-08, 1402/10/18

Registrant information

Name
Afzal Shabbir
Name of organization / entity
Armed Force Postgraduate Medical Institute (AFPGMI)
Country
Pakistan
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+92 313 5158969
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afzalshabbir68@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-16, 1402/05/25
Expected recruitment end date
2024-02-15, 1402/11/26
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasound guided femoropopliteal block versus spinal anesthesia for ankle surgery

Public title

Comparison of ultrasound guided femoropopliteal block versus spinal anesthesia for ankle surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Included all ASA-I and II male and female patients between ages 25-55 years presenting for surgical fixation of malleolar fracture of the ankle.

Exclusion criteria:

Included patients with major cardiac or respiratory disease, patients with failed spinal or femoropopliteal block after three unsuccessful attempts. Patients allergic to local anesthetics including bupivacaine , lignocaine and steroids including dexamethasone. Patients with malignancy or metastatic disease, pregnant females and patients unwilling to be included in the study

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **190**

More than 1 sample in each individual

Number of samples in each individual: **1**

1

Randomization (investigator's opinion)

Randomized

Randomization description

The trail randomized all patients as per the inclusion criteria furnished. The patients were divided into the spinal group and the femoropopliteal block group. Once the patients were divided into the two groups, an informed written consent was taken, and patients in both groups were explained in detail about the procedure and possible complications. Standards monitoring including non-invasive blood pressure, heart rate, capnography and ECG were attached to participants in both groups.

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

Ethical comiittee of combined military hospital

Street address

Tamizudin road , lalkurti rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

CMH/RWP

Health conditions studied

1

Description of health condition studied

Ankle surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

We conclude that spinal anesthesia provides early sensory and motor onset but femoropopliteal block is superior when comparing block duration and total dose of analgesia needed in 24 hours post-operatively.

Timepoint

24 hours post operative

Method of measurement

By measuring the logevity of the block

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Spinal anesthesia was administered in Group S using a standard 27 G Braun spinal needle in the L3-L4 spinal space under strict aseptic measures by a consultant anesthetist and 0.5% hyperbaric bupivacaine using a volume of 2.5 ml was administered. Onset and quality of sensory and motor block was checked and re-assessed every 2 minutes using the modified Bromage scale for motor and cold spray method for check for

sensory block integrity until an effective sensory level was achieved for spinal dermatomal level T12 and below and motor block effectiveness with a Bromage score of 1.

Category

Treatment - Other

2

Description

Control group: Patient in the femoropopliteal block group were administered the block in prone position for the popliteal block blocking the tibial and common peroneal nerves in the popliteal space using 15ml of 0.5%bupivacaine with 2mg dexamethasone. Patients were then turned supine and 5ml of 0.5%bupivacaine with 0.5mg dexamethasone was administered in the femoral sheath for the femoral block. Both the blocks were performed under strict aseptic measures by a consultant pain specialist following standard guidelines furnished by NYSORA. Onset of the block was checked and re-assessed every two minutes until sensory and motor blocks were achieved as in the spinal group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military hospital

Full name of responsible person
Afzal shabbir

Street address
H2JW+9V8, CMH Rd, Rawalpindi, Punjab

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+92 51 9273426

Email
afzalshabbir68@gamil.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined military hospital

Full name of responsible person
Dr khalid buland

Street address
Tamizudin road , lalkurti rawalpindi

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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
Combined military hospital

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
Armed Forces Post Graduate Medical Institute

Full name of responsible person
Afzal shabbir

Position
Registrar Anesthesia

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Itefaq town nai abadi kirpa road islamabad

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Rawalpindi

Province
Punjab

Postal code
46000

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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Armed Forces Post Graduate Medical Institute

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Person responsible for updating data

Contact

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

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