Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of tibialis posterior nerve block on postoperative pain and functional outcomes of patients undergoing hallux valgus surgery

Protocol summary

Study aim
The main aim of this study is to compare the two methods of spinal block and posterior peripheral ankle block on the pain scale, sleep pattern, and function among patients after hallux valgus deformity surgery.

Design
Two arms parallel-group randomised trial with blinded postoperative care and outcome assessment . Patients are categorized in groups based on randomization blocks.

Settings and conduct
Patients undergo spinal anesthesia after surgery routinely. In this study, people will either have the spinal block or be randomly divided into a group that will have both a spinal block and an ankle peripheral block at the same time. The person who performs postoperative measurements and the patients themselves are blind to study.

Participants/Inclusion and exclusion criteria
Patients in the age groups of 20 to 60 years.Exclusion criteria: People under 20 years of age, congenital deformity, Osteoporosis, patients with bilateral involvement, and patients with cardiopulmonary diseases.

Intervention groups
Two groups of 30 people and the first group is placed under the posterior tibial block at the same time and the second group has only a spinal block.

Main outcome variables
Pain, fentanyl dosage and sleep status of patients during 24 hours after surgery and AOFAS score for the performance after 2 weeks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200525047569N1**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-23, 1400/07/01**
Update count: **0**

Registration date
2021-09-23, 1400/07/01

Registrant information

Name
Amir Sabaghzadeh irani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2204 6857

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of tibialis posterior nerve block on postoperative pain and functional outcomes of

patients undergoing hallux valgus surgery

Public title
effect of posterior tibial nerve block on hallux valgus surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
age between 20-65 no other previous surgery of foot no rheumatologic disease Lack of sensitivity to anesthetic drugs hallux valgus deformity moderate to severe
Exclusion criteria:
peripheral neuropathy ankle joint degenerative changes ankle joint muscle weekness
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients will be based on simple randomization and with the help of accepted methods of random sequence production based on the web. The randomizer.org site will be used by filling in the information on the number of patients, two target groups, assigning an equal number in each group, and selecting non-duplicate numbers in this plan. Based on the random sequence numbers generated at the site, patients will be divided into two groups of 30 people under intervention (A) and 30 people in the "Spinal Block" control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
patient do not know that if the anesthetic agent is injected for them in ankle joint and the outcome assessment is done by a person who does not know about the injected drug
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
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Province
Tehran
Postal code
1985717443
Approval date
2021-03-09, 1399/12/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.1342

Health conditions studied

1

Description of health condition studied
Ptients with hallus valgus deformity
ICD-10 code
M20.10
ICD-10 code description
Hallux valgus (acquired), unspecified foot

Primary outcomes

1

Description
VAS (visual analog score)
Timepoint
6,12,24 hours after hallux valgus deformity surgery
Method of measurement
VAS (visual analogue score)

2

Description
Fentanyl intake every 6 hours after hallux valgus surgery
Timepoint
6,12,24 hours after hallux valgus deformity surgery
Method of measurement
Based on patient addmission profile in orthopedic ward

3

Description
AOFAS (American orthopedic association foot and ankle surgery) score
Timepoint
6,12,24 hours after hallux valgus deformity surgery
Method of measurement
The American Orthopedic Foot and Ankle Score (AOFAS) questionnaire

Secondary outcomes

1

Description
Sleep hours during 24 hours after hallux valgus deformity surgery
Timepoint
During 24 hours after surgery
Method of measurement
Patients record in orthopedic ward

Intervention groups

1

Description
Intervention group: peripheral nerve blockage of posterior tibial concurrent with spinal block of hallux valgus surgery.5 ml bupivacaine 0.5% will be administered to posterior tibial nerve, at medial malleolar level and posterior to pulsation of the posterior tibial artery.
Category
Treatment - Other

2

Description
Control group: Spinal nerve block after hallux valgus deformity surgery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e tajrish hospital
Full name of responsible person
Amir Sabaghzadeh
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Tajrish Sq., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Intl_office@sbmu.ac.ir
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
Amir Sabaghzadeh
Position
Tehran
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
From the beginning of winter 1400

When the data will become available and for how long
From the beginning of winter 1400

To whom data/document is available
From the beginning of winter 1400

Under which criteria data/document could be used
From the beginning of winter 1400

From where data/document is obtainable
From the beginning of winter 1400

What processes are involved for a request to access data/document
From the beginning of winter 1400

Comments
From the beginning of winter 1400