

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2204 6857

Email address

dramirsabbaghzadeh@gmail.com

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 weakness

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
Tehran
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 admission 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

Street address

Tajrish Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

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

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

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

Orthopedics

Street address

Tajrish square, Shohada-e tajrish hospital

City

Tehran

Province

Tehran

Postal code

تهران - میدان تجریش

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

Person responsible for scientific 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

Orthopedics

Street address

Tajish suare. Shohada-e tajrish hospital

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

Person responsible for updating data

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

Orthopedics

Street address

Tajrish square, Shohada-e tajrish hospital

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

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