

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

survey of the effect of posterior tibial and sural nerves block on postoperative pain control patients following ORIF of calcaneus fracture through lateral extensive approach .

Protocol summary

Study aim

survey of the effect of posterior tibial and sural nerves block on postoperative pain control in patients following external reduction and internal fixation of calcaneus fracture through lateral extensive approach

Design

Double Blinded Randomized Clinical Trial

Settings and conduct

50 patients in two groups of 25 will be compared in the Chamran Hospital, Shiraz. Patients in the first group will be under Tibial and Sural nerve block 30 - 60 min before induction of anesthesia by injecting 10 ml of bupivacaine 0.5% in the superior aspect of internal maleolous and then 10 ml of 0.5 % bupivacaine in the lateral maleolous. While patients in the control group undergoing surgery without any nerve block.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with distal fracture of the calcaneus and candidate for external reduction and internal fixation of calcaneus fracture through lateral extensive approach; age 18 to 55 years old; (ASA I-II); Exclusion criteria: Consumption of analgesic drugs or opiate, renal failure; hepatic failure and BMI > 35

Intervention groups

Intervention group: Patients in group B will be under Tibial and Sural nerve block 30 - 60 min before induction of anesthesia by injecting 10 ml of bupivacaine 0.5% in the superior aspect of internal maleolous and then 10 ml of 0.5 % bupivacaine in the lateral maleolous. Control group: patients in the control group will be undergo of surgery without any nerve block.

Main outcome variables

Pain and time of the first demand for morphine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180922041084N1**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **prospective**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Maryam Tabibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3628 1460

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

survey of the effect of posterior tibial and sural nerves

block on postoperative pain control patients following ORIF of calcaneus fracture through lateral extensive approach .

Public title
survey of the effect of posterior tibial and sural nerves block on postoperative pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Distal fracture of the calcaneus bone and the candidate of the surgical reduction and internal fixation Age18 - 55 years old ASA I-II
Exclusion criteria:
The patient has a history of misuse of any analgesic or opiate Renal failure Hepatic failure Localized infection in the affected leg BMI of> 35

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized according to the charts which was derived from www.randomization.com site.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the person evaluating the patient after the surgery are unaware of the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features
Double blind randomize clinical trial

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz

University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2018-09-01, 1397/06/10
Ethics committee reference number
IR.SUMS.MED.REC.1397.142

Health conditions studied

1

Description of health condition studied

Fracture of calcaneus

ICD-10 code

S92.00

ICD-10 code description

Unspecified fracture of calcaneus

Primary outcomes

1

Description

First demand for morphine

Timepoint

Post-operative

Method of measurement

Observation

2

Description

Pain

Timepoint

Every 5 min in the recovery room and every 2 hours in the ward at the first 6 hours and then every 4 h until 24 h.

Method of measurement

NRS

Secondary outcomes

1

Description

Patients Satisfaction

Timepoint

Postoperatively

Method of measurement

Likert Scale

Intervention groups

1

Description

Intervention group: Patients will be placed half an hour before entering the operating room by injecting 10 ml of bupivacain 0.5% in the superior medial ankle and then 10 ml of 0.5% bupivacaine in the supperior aspect of lateral ankle under the posterior tibial nerve block and Sural nerve after induction of anesthesia Surgery will be performed.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will be undergo surgery without posterior Tibial and Sural nerve block.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Bitahamzeh Moghadam

Street address

Chamran Blvd/Chamran Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Younes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Bitahamzeh Moghadam

Position

پزشک / ارزیدنت بیهوشی

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Arash Farbood

Position

Fellowship of pain/Anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Maryam Tabibzadeh
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Medical Doctor
Latest degree
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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

It is against our policy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available