Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the efficacy of triamcinolone and dexmedetomidine injection in the treatment of pain caused by plantar fasciitis

Protocol summary

Study aim
Comparison of the efficacy of triamcinolone and dexmedetomidine injection in the treatment of pain caused by plantar fasciitis

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 40 patients. Block randomization method was used.

Settings and conduct
40 participants who met the entry criteria, among the patients who were candidates for dexmedetomidine/triamcinolone injection, referring to the pain clinic of Akhtar Hospital in 2022, were randomly divided into two control (triamcinolone) and intervention (dexmedetomidine) groups. Blinding is a double-blind method, and the patient and the outcome assessor will be unaware of which group they are in.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 years and older; patients with initial complaint of heel pain after weight bearing after a period of rest; chronic heel pain of three months or more without evidence of acute trauma to the heel; Pain score more than 5 after removal The first step is to seek rest. Exclusion criteria: mechanical posterior heel pain; traumatic heel pain; arthritic heel pain; skin ulcer around the heel; acute infection; diabetes; sensory neuropathy; peripheral vascular disease/autoimmune disease; fibromyalgia.

Intervention groups
Intervention group (dexmedetomidine-local anesthetic): Injection of 1 microgram per kilogram of dexmedetomidine plus 2 ml lidocaine 2% under ultrasound guidance with a 22-gauge needle, after prepping the injection site with 1% betadine, with a standard approach in the space between the plantar fascia and periosteum is performed. The injection is done in one session. Control group: triamcinolone: injection of one milliliter (40 milligram) of triamcinolone plus 2 ml of lidocaine 2%. The injection method is similar to the intervention group.

Main outcome variables
Pain Level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170423033615N2**
Registration date: **2022-12-02, 1401/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-02, 1401/09/11**
Update count: **0**

Registration date
2022-12-02, 1401/09/11

Registrant information

Name
Mahshid Ghasemi

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-30, 1401/09/09

Expected recruitment end date
2023-03-18, 1401/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of triamcinolone and dexmedetomidine injection in the treatment of pain caused by plantar fasciitis

Public title
Comparison of the effect of triamcinolone and dexmedetomidine injections in the treatment of heel pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 and above Patients with initial complaint of heel pain after weight bearing after a period of rest Heel pain and plantar fasciitis for more than three months Patients with unilateral chronic plantar fasciitis Failure to respond to conservative treatments Pain that goes away after a few minutes of walking but returns after prolonged walking or standing Pain caused by palpation of medial calcaneal tuberosity, dorsiflexion of the foot passively Chronic heel pain of three months or more without evidence of acute trauma to the heel VAS > 5 after taking the first step following rest Patients with satisfaction to participate in the study
Exclusion criteria:
Mechanical pains in the posterior part of the heel in the form of Achilles tendonitis/bursitis Neurological heel pain caused by nerve rupture Heel arthritis pain Traumatic heel pain Bilateral plantar fasciitis Heel pain for more than three months Skin ulcer around the heel and treatment of that area Sciatica pain; benign and malignant tumors; acute infection; diabetes; sensory neuropathy; peripheral vascular disease / autoimmune disease; fibromyalgia; chronic fatigue syndrome Light sensitivity disorder Pregnancy and breastfeeding
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done as a block randomization method. So, initially, in the Excel software, there are 6 blocks of 4 as (AA, BB), (BB, AA), (AB, BA), (BA, AB). (AB, AB), (BA, BA) are prepared and then these blocks will be arranged from one to six. A is the confirmation of the treatment or intervention group and B is the confirmation of the control group. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned to the treatment or control groups. The random process of selecting blocks and assigning people to the intervention and control groups will continue until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
For the study subjects, before the random assignment, it is explained how the work process is and they may receive one of the two treatments randomly, and the drug used for the subjects is not known in advance, the form of the intervention drug and control and also, the frequency and times of administration of these two will be similar, so that it is not possible for the patient to distinguish them from each other, so the patient will not know which group she is in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Tabnak Street
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-11-12, 1401/08/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.532

Health conditions studied

1

Description of health condition studied
Chronic heel pain and plantar fasciitis
ICD-10 code
M72.2
ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Pain level
Timepoint
Before starting treatment, 4 and 12 weeks after injection
Method of measurement
Visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 1 microgram per kilogram of dexmedetomidine plus 2 ml lidocaine 2% under ultrasound guidance with a 22-gauge needle, after prepping the injection site with 1% betadine, is performed with a standard approach in the space between the plantar fascia and the periosteum. The injection is done in one session.
Category
Treatment - Drugs

2

Description
Control group: injection of one milliliter (40 milligram) of triamcinolone plus 2 ml of lidocaine 2%. The injection method is similar to the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Mahshid ghasemi MD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi MD.
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Shahid Arabi st., Yaman St., Shahid Chamran Expressway
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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
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
Mahshid Ghasemi MD
Position
Associate Professor
Latest degree
Subspecialist
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
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
Yes - There is 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
Title and more details about the data/document
The whole data can be shared after unidentifiable people.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only available to scholars working in academic and academic institutions
Under which criteria data/document could be used
Employed in research centers
From where data/document is obtainable
Email to the person responsible for the study (email address: mahshidghasemi@sbmu.ac.ir).
What processes are involved for a request to access data/document
Send email to person responsible for scientific inquiries
Comments