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Comparison of the effectiveness of dextrose infiltrations in the treatment of plantar fasciitis

Submission date
08/03/2026

Recruitment status
No longer recruiting

Registration date
16/03/2026

Overall study status
Completed

Last Edited
16/03/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Plantar fasciitis is one of the most common causes of heel pain and affects approximately 10% of the population during their lifetime. It can significantly reduce physical activity and quality of life. One of the emerging treatments for this condition is prolotherapy with dextrose, a technique that involves injecting a dextrose solution to stimulate tissue repair and reduce pain. Previous studies have shown promising results in terms of pain relief and functional improvement.
However, there is still uncertainty regarding the most effective injection site. Some clinicians inject the solution around the affected tissue (perilesional), while others inject directly into the damaged fascia (intralesional). The aim of this study is to compare the effectiveness of these two techniques in reducing pain and improving foot function in patients with plantar fasciitis.

Who can participate?
Adults aged between 30 and 65 years who have been diagnosed with plantar fasciitis and have had symptoms for at least 30 days may participate in the study. Participants must show an increased plantar fascia thickness on ultrasound (greater than 0.4 cm) and must provide written informed consent.
People will not be eligible if they have systemic diseases affecting the musculoskeletal system, other causes of plantar pain (such as autoimmune diseases or nerve entrapment), recent treatments for foot conditions within the previous three months, or conditions that may interfere with walking or foot function.

What does the study involve?
Participants will be randomly assigned to one of two treatment groups. One group will receive perilesional injections of 20% dextrose around the plantar fascia, while the other group will receive intralesional injections directly into the affected fascia.
All injections will be performed under ultrasound guidance. Each participant will receive three treatment sessions, separated by two-week intervals.
Participants will undergo clinical and ultrasound assessments before treatment and during follow-up visits at 30, 60, 120 days and 12 months after the intervention. Pain levels will be measured using a visual analogue scale (VAS), and foot function will be assessed using the Foot Function Index (FFI).

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in heel pain and an improvement in foot function. The treatment aims to stimulate tissue repair and reduce symptoms associated with plantar fasciitis. The risks associated with the procedure are considered minimal. Possible side effects may include temporary pain at the injection site, mild inflammation, or, in rare cases, local infection. The procedure will be performed under ultrasound guidance and with local anaesthesia to minimize discomfort and reduce risks.

Where is the study run from?
The study will be conducted at Clínica Podológica Álvaro Saura, located in Mairena del Aljarafe (Seville, Spain), which has the necessary facilities and equipment for clinical research and ultrasound-guided procedures.

When is the study starting and how long is it expected to run for?
February 2025 to March 2026

Who is funding the study?
Clínica Podológica Álvaro Saura (Spain)

Who is the main contact?
Dr Álvaro Saura Sempere, alvarosaura@gmail.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Comparison of the effectiveness of dextrose infiltrations in the treatment of plantar fasciosis: analysis of the impact of the perilesional versus intralesional treatment zone

Study objectives

1. To evaluate pain reduction in patients with plantar fasciitis treated with perilesional injections of 20% dextrose prolotherapy.
2. To evaluate pain reduction in patients with plantar fasciitis treated with intralesional injections of 20% dextrose prolotherapy.
3. To analyze functional foot recovery in patients treated with perilesional injections of 20% dextrose prolotherapy.
4. To analyze functional foot recovery in patients treated with intralesional injections of 20% dextrose prolotherapy.
5. To compare the effectiveness of perilesional injections of 20% dextrose prolotherapy in terms of recovery time.
6. To compare the effectiveness of perilesional injections of 20% dextrose prolotherapy in terms of recovery time.
7. To examine the incidence of adverse effects associated with perilesional infiltration techniques of 20% dextrose prolotherapy.
8. To examine the incidence of adverse effects associated with intralesional infiltration techniques of 20% dextrose prolotherapy.
9. To determine the influence of demographic and clinical factors on the response to treatment with intralesional infiltrations of 20% dextrose prolotherapy.
10. To determine the influence of demographic and clinical factors on the response to treatment with perilesional infiltrations of 20% dextrose prolotherapy.
11. To compare the thickness of the plantar fascia in patients with plantar fasciosis treated with perilesional and intralesional infiltrations of 20% dextrose prolotherapy with the measurement obtained for the plantar fascia at the start of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/02/2025, Comité de Ética Hospital Clínico San Carlos (Profesor Martín Lagos, s/n. - Puerta G - 4ª Norte Madrid, Madrid, 28040, Spain; +34 (0)91 704 41 58 / (0)91 704 41 59; ceic.hcsc@salud.madrid.org), ref: C.I. 25/022-EC_X_Tesis

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Plantar fasciosis

Interventions
The groups will be randomly assigned, and each group will be assigned to a specific infiltration site:
1. Group 1 (perilesional infiltration): Patients will be treated with perilesional dextrose infiltration
2. Group 2 (intralesional): Patients will be treated with dextrose infiltration into the affected fascial tissue

Patients will be given a sealed envelope labeled Group A or Group B. Group A will receive intralesional infiltration, and Group B will receive perilesional infiltration. Participants will not know which group they have been assigned to. The envelopes will be distributed equally until both research groups are complete, following the rules of simple random assignment. In both groups, the injections will be performed under ultrasound guidance.

The clinical and ultrasound measurements of the participants will be performed following a standardized protocol before the start of treatment and during the different annual follow-up visits. For pain assessment, the Visual Analog Scale (VAS) will be used, asking the patient to indicate the intensity of pain on a 10 cm line, with the value being recorded in millimeters for analysis. Foot function will be evaluated using the Foot Function Index (FFI), a validated questionnaire that will quantify the functional impact of the pathology on activities of daily living.

Measurement of plantar fascia thickness will be performed using musculoskeletal ultrasound with a high-frequency linear transducer (10–15 MHz). The patient will be positioned in the prone position with the foot relaxed and in a neutral position. The transducer will be placed in the longitudinal plane over the medial region of the heel, at the level of the insertion of the plantar fascia on the medial tubercle of the calcaneus, and the fascial thickness will be recorded in millimeters from the superior to the inferior border of the structure. All measurements will be performed by the same operator to reduce inter-observer variability.

Injections with 20% dextrose solution will be administered using an ultrasound-guided technique to ensure accurate localization of the target tissue. The needle will be introduced in a medial-to-lateral direction until reaching the plantar fascia, and the corresponding volume will be deposited under direct ultrasound supervision. This procedure will be repeated in four sessions, separated by 2-week intervals.

The recording of the variables VAS, FFI, and fascial thickness will be carried out systematically at the baseline visit, before each injection session, and during subsequent follow-up visits, with the final measurement being performed 1 year after the start of treatment. This measurement system will allow the collection of continuous and reproducible data to assess the clinical and structural evolution of the plantar fascia throughout the study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Plantar fascia thickness measured using ultrasound at 0, 2, 4, 6, 8, 12, 32, 52 weeks

2. Pain measured using Visual Analog Scale (VAS) at 0, 2, 4, 6, 8, 12, 32, 52 weeks

3. Patient functionality measured using Foot Functional Index (FFI) at 0, 2, 4, 6, 8, 12, 32, 52 weeks

Key secondary outcome(s)

Completion date
05/03/2026

Eligibility

Key inclusion criteria
1. Patients aged between 30 and 65 years
2. Present symptoms compatible with plantar fasciitis of at least 30 days of evolution
3. Presence of ultrasound thickness greater than 0.4 cm
4. Signing of informed consent to participate in the study

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
56

Key exclusion criteria
1. Suffering from systemic diseases or morphofunctional alterations unrelated to the foot that could affect the ankle and foot, potentially leading to significant clinical discrepancies in the lower limbs, asymmetries or evident clinical scoliosis
2. Having received any treatment (medical, orthopedic and/or invasive) for the foot in the last 3 months
3. Suffering from plantar pain associated with another condition, such as autoimmune disease or nerve entrapment
4. Difficulties in understanding the instructions necessary during treatment

Date of first enrolment
07/02/2025

Date of final enrolment

28/02/2025

Locations

Countries of recruitment
Spain

Sponsor information

Organisation
Universidad Complutense de Madrid

ROR
https://ror.org/02p0gd045

Funder(s)

Funder type

Funder Name
Clínica Podológica Álvaro Saura

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available