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Evaluating the effectiveness of load restriction in enhancing recovery after autologous whole-blood injection for plantar fasciitis

Submission date
04/08/2024

Recruitment status
No longer recruiting

Registration date
09/08/2024

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Plantar fasciitis is a common condition causing heel pain, particularly in individuals who are physically active or stand for long periods. This study investigates whether resting the foot after receiving an autologous whole-blood injection (AWBI) leads to faster recovery compared with continuing normal activities. Participants will be divided into two groups: one that follows a rest protocol and one that resumes normal activities immediately. The goal is to determine which approach results in better pain relief and quicker recovery.

Who can participate?
Adults aged 20 years and older diagnosed with plantar fasciitis who have not responded to other treatments are eligible. Participants must be able to follow study procedures and not have other health conditions that might interfere with the study results.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will rest their foot and use crutches for three days after the injection, while the other group will walk normally. Pain levels and recovery progress will be monitored and assessed at various time points over three months.

What are the possible benefits and risks of participating?
Participants might benefit from access to potentially effective treatment and contribute valuable information to improve future care. Possible risks include temporary discomfort from using crutches or changes in pain levels, but participants will be closely monitored to manage any issues.

Where is the study run from?
The study is conducted at Uşak Education and Research Hospital (Uşak Eğitim ve Araştırma Hastanesi), Turkey

When is the study starting and how long is it expected to run for?
July 2022 to November 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Oğuzhan Gökalp, oguzhan.gokalp@usak.edu.tr, oguzhangokalp@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
In patients with chronic plantar fasciitis, does post-injection load restriction compared to no load restriction improve recovery time and pain reduction following autologous whole-blood injection?

Study objectives
Current study hypothesis as of 13/01/2025:
Hypothesis 1: Load restriction following autologous whole-blood injection (AWBI) for plantar fasciitis will result in a significantly faster reduction in pain compared to no load restriction.

Hypothesis 2: Patients undergoing load restriction after AWBI will demonstrate improved pressure pain threshold (PPT) scores at 3 and 30 days post-treatment compared to those who do not follow load restriction.

Hypothesis 3: Load restriction will lead to a quicker return to normal activities and a decreased need for analgesics compared to patients who do not adhere to load restriction protocols.

Hypothesis 4: The benefits of load restriction on recovery from plantar fasciitis will be most pronounced in the early recovery phase (up to 30 days post-treatment), with minimal long-term differences (minimum one year) compared to no load restriction.

Previous study hypothesis:
Hypothesis 1: Load restriction following autologous whole-blood injection (AWBI) for plantar fasciitis will result in a significantly faster reduction in pain compared to no load restriction.

Hypothesis 2: Patients undergoing load restriction after AWBI will demonstrate improved pressure pain threshold (PPT) scores at 3 and 30 days post-treatment compared to those who do not follow load restriction.

Hypothesis 3: Load restriction will lead to a quicker return to normal activities and a decreased need for analgesics compared to patients who do not adhere to load restriction protocols.

Hypothesis 4: The benefits of load restriction on recovery from plantar fasciitis will be most pronounced in the early recovery phase (up to 30 days post-treatment), with minimal long-term differences (beyond 90 days) compared to no load restriction

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/03/2023, Uşak University Clinical Research Ethics Committee (Uşak Üniversitesi Rektörlüğü, Hukuk Müşavirliği, 1 Eylül Yerleşkesi, İzmir Yolu 8. km. Rektörlük Binası 3. kat No: 322, Uşak, 64200, Türkiye; +90 276 2212180 / 1830; hukuk@usak.edu.tr), ref: 85-85-15

Primary study design
Interventional

Study design
Single-center prospective single-blinded randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Recovery from plantar fasciitis in adults undergoing autologous whole-blood injection with and without load restriction

Interventions
In this interventional study, adult patients diagnosed with plantar fasciitis who did not respond to at least two months of conservative treatment are randomly assigned to one of two groups.

Intervention Groups:

Load Restriction Group: Patients in this group receive autologous whole-blood injections (AWBI) for plantar fasciitis. Following the injection, they are instructed to refrain from weight-bearing on the treated foot for 3 days and use double Canadian crutches to assist with mobility. This group is monitored for adherence to the load restriction protocol and assessed at the 4th, 30th, and 90th days post-injection.

No Load Restriction Group: Patients in this group also receive AWBI but are permitted to walk normally after the procedure. They are similarly assessed at the 4th, 30th, and 90th days post-injection.

Randomization: Participants are randomly assigned to the load restriction or no load restriction groups based on their admission order. Randomization is performed by a physician who instructs the participants on the specific protocol for their assigned group.

Measurements and Assessments: Pain levels are evaluated using the Visual Analog Scale (VAS) and pressure pain thresholds (PPT) are measured with a digital algometer. The need for analgesics and the time taken to return to normal activities are also recorded. Data are analyzed to compare recovery outcomes between the two groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 13/01/2025:
The following primary outcome measures are assessed at baseline, 3 days, 30 days, 90 days, and one-year post-treatment:
1. Pain intensity measured using a Visual Analog Scale (VAS)
2. Pressure pain threshold (PPT) measured using a digital algometer

Previous primary outcome measure:
The following primary outcome measures are assessed at baseline, 3 days, 30 days, and 90 days post-treatment:
1. Pain intensity measured using a Visual Analog Scale (VAS)
2. Pressure pain threshold (PPT) measured using a digital algometer

Key secondary outcome(s)
Current secondary outcome measures as of 13/01/2025:
1. Analgesic Use measured using a self-reported diary recorded daily for 90 days post-treatment
2. Time to Return to Normal Activities measured using a patient-reported assessment of when they can comfortably resume daily activities at 3 days, 30 days, and 90 days post-treatment

Previous secondary outcome measures:
1. Analgesic Use measured using a self-reported diary recorded daily for 90 days post-treatment
2. Time to Return to Normal Activities measured using a patient-reported assessment of when they can comfortably resume daily activities at 3 days, 30 days, and 90 days post-treatment
3. Functional Improvement measured using the Foot Function Index (FFI) questionnaire at baseline, 30 days, and 90 days post-treatment

Completion date
05/11/2024

Eligibility

Key inclusion criteria
1. Age Range: 20 to 65 years old
2. Diagnosis: Diagnosed with plantar fasciitis that has not responded to at least two months of

conservative treatment
3. Treatment History: No prior history of autologous whole-blood injections for plantar fasciitis
4. Consent: Willingness to provide informed consent for participation in the study
5. Mobility: Capable of using Canadian crutches if assigned to the load restriction group
6. Health Status: No significant systemic diseases or conditions affecting the foot or plantar fascia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
149

Key exclusion criteria
1. Heavy Labor Employment: Participants who are employed in jobs involving heavy physical labor
2. Use of Immunomodulatory Drugs: Individuals who are currently using immunomodulatory medications
3. Previous Injection History: Patients with a history of previous injections for plantar fasciitis
4. Bilateral Plantar Fasciitis: Individuals diagnosed with plantar fasciitis in both feet
5. Previous Foot Surgery: Patients who have undergone foot surgery in the past
6. Local Anesthetic Sensitivity: Individuals with known sensitivity or adverse reactions to local anesthetics
7. Rheumatological Diseases: Participants with diagnosed rheumatological conditions
8. Autoimmune/Neuropathic Diseases: Individuals with autoimmune or neuropathic disorders

Date of first enrolment
02/03/2023

Date of final enrolment
04/11/2023

Locations

Countries of recruitment

Türkiye

Study participating centre
Uşak Eğitim ve Araştırma Hastanesi
Fevzi Çakmak Mahallesi Denizli Caddesi No:4
Uşak
Türkiye
64100

Sponsor information

Organisation
Usak University

ROR
https://ror.org/05es91y67

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
For the current study, the data-sharing plan is as follows:

The datasets generated during and/or analysed during the current study will be available upon request from:
Contact Name: Oğuzhan Gökalp
Email Address: oguzhan.gokalp@usak.edu.tr, oguzhangokalp@gmail.com

Type of Data to be Shared:
Individual Participant Data (IPD), including demographic information, treatment details, and outcome measures.

When the Data Will Become Available:
Data will be made available upon publication of the study results.

Duration of Data Availability:
Data will be available for 5 years from the date of publication.

Access Criteria:
Data will be shared with researchers who have a legitimate interest in conducting analyses relevant to the study's objectives.
Requests must be made in writing, specifying the purpose of the analysis.

Mechanism of Data Sharing:
Data will be provided via a secure data transfer method (e.g., encrypted email or secure file-sharing service).

Consent from Participants:
Consent for data sharing was obtained from all participants as part of the informed consent process.

Comments on Data Anonymisation:
All data will be anonymised to protect participants' privacy. Identifiable information will be removed or masked.

Ethical or Legal Restrictions:
Data sharing will comply with institutional ethics guidelines and relevant data protection regulations.

Additional Comments:
Researchers requesting access to data will be required to sign a data use agreement to ensure the data is used responsibly and only for the intended purpose.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			28/01/2025	No	No
Participant information sheet	Patient registration and follow-up form		09/08/2024	No	Yes