Effectiveness of radial shock wave treatment or tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain

Submission date	Recruitment status	Prospectively registered
25/10/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/11/2009	Completed	☐ Results
Last Edited	Condition category	Individual participant data
09/10/2015	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Effectiveness of radial shock wave treatment or tissue-specific plantar fascia-stretching in patients with chronic plantar heel pain: a randomised controlled observer-blinded trial

Study objectives

Null hypothesis:

Radial shock wave treatment or tissue specific stretching or radial shock wave treatment in combination with tissue specific stretching provide comparable outcomes at 4 months follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the "Orthopädie im Centrum", Alzey, Germany, approved on the 3rd July 2005

Study design

Randomised controlled observer-blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Plantar fasciopathy

Interventions

Patients are randomly allocated to three sessions of radial shock wave treatment or to plantar fascia stretching:

Group I: plantar fascia-specific stretching (PFSS), 3 x per day, for eight weeks

Group II: Radial shock wave therapy (RSWT), performed 3 x in weekly intervals

Group III: PFSS + RSWT

Follow-up: at 2 months, four months, and 15 months from baseline. Main follow-up is 4 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Overall heel pain reduction measured by the percentage change of the VAS composite score 4 months after beginning of treatment compared with baseline, with last value carried forward (LVCF) replacement of missing values with the last recorded value.

Key secondary outcome(s))

- 1. 6-point Likert scale (fully recovered or significantly improved as success criteria) at 0, 4 and 12 months from baseline
- 2. Plantar fascia thickness measured before and 4 months and 15 months from baseline
- 3. Roles and Maudsley Score measured before and 4 months and 15 months from baseline
- 4. Number of patients achieving 80 points at at month 4, and at month 15 from baseline in the patient's function assessed using the validated 100-point AOFAS (American Orthopaedic Foot and Ankle Society) Ankle-Hindfoot-Score

Completion date

01/01/2010

Eligibility

Key inclusion criteria

- 1. History of plantar fasciitis for more than 6 months
- 2. Numeric Rating Scale (NRS) score persistingly (at least 5 points for pain during the first few steps of walking in the morning)
- 3. Localised pain on palpation of the proximal plantar fascia
- 4. Be willing to abstain from any other treatments or medications during the treatment and follow-up period

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Kev exclusion criteria

- 1. Less than 18 years of age
- 2. Receiving local injections less than 3 months prior to the randomisation visit
- 3. Receiving physical therapy less than 3 months prior to the randomisation visit
- 4. Receiving non-steroidal anti-imflammatory drugs (NSAIDs) for any chronic conditions whether or not related to plantar fasciitis prior to the randomisation visit
- 5. Receiving systemic therapeutic anticoagulants
- 6. Bilateral plantar fasciitis
- 7. History and/or physical findings of lower extremity dysfunction, local arthritis, generalised poly-arthritis, rheumatoid arthritis, ankylosing spondylitis, local arthrosis
- 8. Neurologic abnormality (changes of deep tendon reflexes, motor or sensory deficit)
- 9. Arthrosis of the foot or ankle, as confirmed by x-ray diagnosis (AP, lateral views)
- 10. Previous surgery of the foot
- 11. Participation in a Workman's Compensation Program or plans to apply for the Program
- 12. Thrombopathy, infection, tumour, diabetes mellitus, systemic lupus, severe cardiac disease or other severe systemic diseases
- 13. Pregnancy

Date of first enrolment

01/07/2007

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

Germany

Study participating centre OrthoTrauma Evalaution Center Mainz

Germany D-55130

Sponsor information

Organisation

OrthoTrauma Evaluation Center (Germany)

Funder(s)

Funder type

Research organisation

Funder Name

OrthoTrauma Evaluation Center (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information si

Participant information sheet 11/11/2025 11/11/2025 No