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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/07/2007

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

Age group
Adult

Sex
Both

Target number of participants
250

Key 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
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Sponsor information

Organisation
OrthoTrauma Evaluation Center (Germany)

Sponsor details
Oppenheimer Str. 70
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
OrthoTrauma Evaluation Center (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration