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Plantar Fascia-Specific Stretching (PFSS) versus Radial Shock Wave Therapy (SWT) as Initial Treatment of Plantar Fasciopathy

Submission date
23/11/2009

Recruitment status
No longer recruiting

Registration date
03/12/2009

Overall study status
Completed

Last Edited
03/12/2009

Condition category
Musculoskeletal Diseases

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

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
Plantar Fascia-Specific Stretching (PFSS) versus Radial Shock Wave Therapy (SWT) as Initial Treatment of Plantar Fasciopathy: a randomised controlled observer-blinded trial

Study objectives
Null hypothesis: PFSS or SWT for patients with a previously untreated unilateral plantar fasciitis (PF) of up to six-week duration provide comparable outcomes at 2 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 4th 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
Group I: plantar fascia-specific stretching, 3x per day, for eight weeks
Group II: Shock wave therapy, performed 3x in weekly intervals

Follow-up: at 2 months, 4 months, 15 months from baseline

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary efficacy endpoint is prospectively defined as change of the sum score of the pain subscale of the Foot function Index (PS-FFI) from baseline to month two. Further primary efficacy criteria are the change of item ´2` of the PS-FFI from baseline to month two, and the response rate to question #6 (satisfaction with treatment) of the subject-relevant outcome measures (SROM) questionnaire at month two from baseline.

Secondary outcome measures
Change of the sum score of the PS-FFI from baseline to month four, and to month fifteen; change of the score of item ´2` of the PS-FFI from baseline to month four, and to month fifteen; association of treatment with response rates of the SROM questionnaire at month two, at month four, and at month fifteen.

Overall study start date
01/08/2005

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. History of plantar fasciitis for less than 6 weeks
2. Numeric Rating Scale (NRS) score ≥ 6 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
100

Key exclusion criteria
1. < 18 years of age
2. Receiving local injections prior to the randomisation visit
3. Receiving physical therapy prior to the randomisation visit
4. Receiving NSAIDs for any chronic conditions whether or not related to plantar fasciitis prior to the randomization 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 Workmans 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
01/08/2005

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Germany

Study participating centre
OrthoTrauma Evaluation Center
Mainz
Germany
D-55130

Sponsor information

Organisation
OrthoTrauma Evaluation Centre (Germany)

Sponsor details
Oppenheimer Str. 70
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

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