ISRCTN03438342 https://doi.org/10.1186/ISRCTN03438342

# 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

**Contact name**
Prof Jan D. Rompe

**Contact details**
OrthoTrauma Evaluation Center
Oppenheimer Str. 70
Mainz
Germany
D-55130

## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

## Key secondary outcome(s))
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.

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

# Funder(s)

**Funder type**
Hospital/treatment centre

**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