

The effects of pathological changes of foot structures on foot function of patients with plantar fasciitis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40798

Source

ToetsingOnline

Brief title

Foot function in plantar fasciitis

Condition

- Tendon, ligament and cartilage disorders

Synonym

Jogger's heel, plantar fasciitis, Plantar fasciopathy

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Roessingh Research and Development;in de vorm van een studenten opdracht

Intervention

Keyword: Foot function, Foot structures, Gait, Plantar fasciitis

Outcome measures

Primary outcome

The passive mobility of the hindfoot and forefoot segment in sagittal, frontal and transverse planes;

Range of motion mobility of the hallux;

Mobility of the hindfoot, midfoot, forefoot and hallux during gait (VICON, Oxford metrics Ltd).

Secondary outcome

Cross-sectional area of the intrinsic forefoot muscles (Ultrasound);

foot function score (5-FFI);

foot posture index (FPI) and Joint alignment and Motion (JAM)

intrinsic foot muscle force (hand held dynamometer);

pain assessment (VAS);

thickness of the plantar fascia (Ultrasound);

kinetics during walking (AMTI forceplate)

Study description

Background summary

Plantar fasciitis is the most common foot impairment and affects approximately 10% of all adults during their life. This disease is tedious and very painful due to degeneration or inflammation of the plantar enthesis of the plantar fascia at the calcaneus insertion site. Complete recovery from PF may take six to eighteen months, regardless whether treatment was used or not. Multiple risk factors for PF have been reported such as obesitas, pes planus/cavus,

diabetes mellitus and frequent running (Goff & Crawford, 2011; Roxas, 2005). Despite of the multiple risk factors studied and reported, little attention has been paid to corresponding impairments of foot structures. Furthermore, most studies are performed on patients with a chronic form of plantar fasciitis. Therefore, at present, the role of foot structural changes on the formation of plantar fasciitis and corresponding effects on foot function is not clear .

Study objective

This explorative study is performed to improve our understanding of possible etiologic factors and the relationships between foot mobility, intrinsic foot muscles and foot segment kinematics during gait for patients with sub-acute and chronic plantar fasciitis.

- The primary goal of this project is assessing the properties of foot structures that possibly play a role in the etiology of PF. The properties of the foot structures of the patients will be compared to those of the control group and associations will be evaluated.
- The secondary aim is recording the effects of PF on movements of segments of the foot during gait. The foot segment movements from patients will be compared to the movements of healthy subjects
- The third aim is to analyse the possible correlations with characteristics/properties of foot structures.

Study design

This study has a cross-sectional design, with one measurement session. In the assessment session at the RRD, foot mobility, questionnaires and muscle force measurements will be performed for all participants. During the walking trial, gait kinetics and kinematics will be assessed for the healthy subjects and the patients with plantar fasciitis.

Study burden and risks

Participation of a subject in this experiment has no direct benefit for him or her. The risk in participation is small because walking is a natural and familiar act and participation will not get in the way of recovery. Regarding the use of ultrasound, Merritt (Merritt, 1989) reports that ultrasound is a safe imaging modality. The World Health Organization supports that ultrasound is a safe and highly flexible imaging tool (World Health Organization, 1998). Therefore, no risks are associated with ultrasound when used once. Furthermore, during all the measurements a physiotherapist will accompany the subjects. Subjects can take rest between the measurements any time they like and may stop the experiment at any time desired.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Unilateral plantar fasciitis
2. Thickness of the proximal plantar fascia is more than 4 mm
3. Pain symptoms (Visual Analog Scale > 5)
4. For patients with (sub)-acute PF: less than 10 weeks of foot complaints

Exclusion criteria

1. Plantar fasciitis complaints that occur after trauma or when other diagnosis such as neuropathies or bone- or tendon diseases occur as well: for example tarsal tunnel syndrome, stress fracture of the calcaneus, Achilles tendinitis
2. Patients with systemic or metabolic diseases

3. Use of walking aids, with exception of insoles
4. Age: younger than 18 or older than 55 years (to exclude elderly patients with degenerative changes)
5. Other foot and ankle conditions that affect joint movements of the ankle during walking
6. Other conditions that have a negative effect on walking

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2014
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO	
Date:	27-05-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48243.015.14
Other	NTR aanvraag 16406