Comparison between types of stretching ortheses in treatment of plantar fasciitis

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We expect that all three treatments are effective. However, the posterior tension night splint might be earlier effective compared to the other treatments.

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

Summary

ID

NL-OMON24109

Source
NTR

Brief title
Fasciitis Plantaris study

Condition

- Tendon, ligament and cartilage disorders

Health condition

Gastrocnemius-soleusstretching Plantar fasciitis: Night splint, Cast Gastrocnemius-soleusstretching fasciitis plantaris Nachtspalk Gips

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Self financing research

Intervention

Outcome measures

Primary outcome

To assess the clinical outcome and evaluate the effectiveness after treatment of plantar fasciitis with a posterior tension night splint (Pro Orthics), soft night splint (Strassbourg sock) or custom made cast for the treatment of plantar fasciitis in a monocenter routine clinical setting.

Our primary endpoint is pain measured with a Numeric Rating Scale (NRS first step pain) at 3 months after starting treatment between the three stretching orthesis.

Secondary outcome

secondary endpoints are the NRS (pain in rest) at three and six months, Foot Function Index (FFI), Foot and Ankle outcome scores (FOAS), compliance and satisfaction questionnaire. These are foot specific questionnaires specifically designed to measure outcome after ankle-foot treatment.

Study description

Background summary

Plantar fasciitis is the most common cause of subcalcaneal heel pain. It is a condition that affects about 10% of the population, frequently with an onset in middle-aged individuals, and accounts many orthopedic outpatient visits due to limited physical activity. Plantar fasciitis is often treated with a stretching ortheses in addition to stretching exercises of the calf musculature. There have been several effective stretching ortheses options mentioned in recent history and frequently prescribed in our hospital such as posterior tension night splint (Pro Orthics), soft night splint (Strassburg sock) and a custom made cast. However, no randomized controlled trials were performed which compares the differences in pain and functional outcome between these three stretching orthesis. The purpose of this randomized study is to evaluate the effectiveness of three conservative options for the treatment of plantar fasciitis in a monocenter routine clinical setting.

Study objective

We expect that all three treatments are effective. However, the posterior tension night splint might be earlier effective compared to the other treatments.

Study design

Our primary endpoint is pain measured with a Numeric Rating Scale (NRS first step pain) at 3 months after starting treatment between the three stretching orthesis. Patient wil be followed till six months.

Intervention

Treatment of plantar fasciitis with:

Group 1: Prefabricated posterior tension night splint (Pro Orthics)

Group 2: Prefabricated soft night splint (Strassburg sock)

Group 3: Custom made cast

Contacts

Public
Reinier Haga Orthopedisch Centrum
J.H. Pasma
Sportlaan 600

Den Haag 2566 MJ
The Netherlands
079- 206 5595
Scientific
Reinier Haga Orthopedisch Centrum
J.H. Pasma
Sportlaan 600

Den Haag 2566 MJ
The Netherlands
079- 206 5595

Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Engels

• Age over 18 years

• Patient with, the subjective and objective signs and symptoms of mechanical plantar fasciitis

• Patients who speak and/or understand Dutch

• Patient who are able and willing to participate in a treatment for 6 months.

Nederlands

Patienten ouder dan 18 jaar

Patienten met objectieve en subjectieve symptomen van mechanische fasciitis plantaris

Patienten die Nederlands spreken en verstaan

Patienten die de mogelijkheden hebben en bereidt zijn om een behandeling te ondergaan voor 6 maanden.

Exclusion criteria

Engels

• Subject is not able to complete the daily questionnaires in Dutch or not being able to fill in the Dutch Questionnaires.

• Patients with heel pain from causes other than plantar fasciitis

• Patients with a history of heel fracture or heel surgery, and systemic inflammatory arthritis.

• Subject, in the opinion of the investigator, is not able to understand this investigation and is not willing and able to perform all study procedures and co-operate with investigational procedures.

• Subject was diagnosed and is taking prescription medications to treat a muscular disorder that limits mobility due to severe stiffness and pain such as fibromyalgia or polymyalgia.

• Subject has participated in a clinical investigation with an investigational product (drug or device) in the last three months.

• Subject has refused voluntary, written informed consent to participate in this randomized controlled trial

Nederlands

Patienten die niet in staan zijn om de Nederlandse vragenlijsten in te vullen of te begrijpen

Patienten met hiel pijn vanwege een andere oorzaak dan fasciitis plantaris

Patienten met een voorgeschiedenis van calcaneusfractuur, calcaneus operaties of systeemaandoening waardoor artritis..

Patient die niet in staat is mo het onderzoek te begrijpen en niet capabel is om aan het onderzoek en de procedure te voldoen,

Patienten die medicatie neemt in verband met spieraandoening waardoor de mobiliteit is aangedaan tgv stijfheid en pijn zoals fibromyalgie en polymyalgia.

Patienten die weigeren een informed consent formulier te ondertekenen.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	02-11-2018
Enrollment:	102
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	16-07-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52618
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7208
NTR-old	NTR7407
Other	METC ZWH : 18-053
CCMO	NL65577.098.18
OMON	NL-OMON52618

Study results