comparison between different types of gastrocnemius-soleus stretching in the treatment of plantar fasciitis: posterior night splint, soft night splint of a custom-made cast.

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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...

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

Summary

ID

NL-OMON52618

Source
ToetsingOnline

Brief title
comparison between different types treatment of plantar fasciitis:

Condition

- Tendon, ligament and cartilage disorders

Synonym
plantar fasciitis, plantar heel pain

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: maatschap orthopedie

Intervention

Keyword: Cast, Gastrocnemius-soleusstretching Plantar fasciitis:, Night splint

Outcome measures

Primary outcome

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.

Primary Objective:

Is there a minimal important difference in pain level (NRS first step pain) between subjects with plantar fasciitis receiving a posterior tension night splint (Pro Orthic), soft night splint (Strassburg sock) or custom made cast after 3 months?

Secondary outcome

Secondary Objective(s):

• Is there a minimal important difference in pain level (NRS first step pain) between subjects with plantar fasciitis receiving a posterior tension night splint ((Pro Orthic), soft night splint (Strassburg sock) or custom made cast after 6 months?

• Is there a minimal important difference in pain level (NRS rest) between subjects with plantar fasciitis receiving a posterior tension night splint (Pro

Orthic), soft night splint (Strassburg sock) or custom-made cast after 3/6 months?

• Is there a minimal clinical important difference in influences daily activities based on functional outcome scores (FFI and FOAS) between the three groups during 3 and 6 months?

• What is the percentage of subject satisfaction after 6 months between the three study groups?

• What is the percentage of patient*s compliance between the three study groups based on nights of wearing in the first three months?

• What is the percentage of additional treatment: immobilisation/ local infiltration with corticosteroid in the three study groups

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

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 multicenter routine clinical setting.

Study design

Monocenter prospective randomized and controlled study. Inclusion will start in September 2018, with a maximum follow of 6 months per patient. The study will be conducted in the Haga Hospital.

Intervention (if applicable): 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

Study burden and risks

We expect no risks associated with participation, due to the nature of the study (filling out questionnaires). The extra burden placed on patient will consist of two times completing four questionnaires at baseline and at three months (T 1) and six months (T2) and a weekly diary for 3 months.

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

• 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.

Exclusion criteria

• 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

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2018
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	08-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	23-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24109
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65577.098.18
OMON	NL-OMON24109

Study results

Date completed:	09-07-2023
Actual enrolment:	81