Effect of insole top covers on pressure relief and satisfaction in patients with diabetes

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To assess the efficacy of different top covers of inlays worn in orthopaedic footwear on the plantar pressure and patient satisfaction in diabetic patients at risk for foot ulceration.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON55590

Source
ToetsingOnline

Brief title
DIATOP

Condition

- Diabetic complications

Synonym
Diabetic foot, diabetic neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetic foot, Insole concepts, Patient satisfaction, Plantar foot pressure

Outcome measures

Primary outcome

Peak plantar pressure

Secondary outcome

Patient satisfaction

In-vivo durability of insole top layer material

Study description

Background summary

Different orthopedic footwear insole concepts have been developed over the last years with the goal to unload the plantar foot of diabetic patients with peripheral neuropathy who require special footwear to protect the foot against ulceration. Being different in using various material properties of the top cover of the insole, these insole concepts may be less or more effective in offloading the diabetic foot. A comparison between these concepts in their offloading efficacy has not been performed to date, but can inform us about what entails effective footwear that may result in the best shoe design for the diabetic foot patient.

Study objective

To assess the efficacy of different top covers of inlays worn in orthopaedic footwear on the plantar pressure and patient satisfaction in diabetic patients at risk for foot ulceration.

Study design

Cross-sectional and interventional study design

Intervention

The patients left and right insole will be covered with two different and

randomly assigned insole top covers that were tested, and wear these for approximately 4 weeks. This will be repeated with two other top covers, that will also be worn for 4 weeks.

Study burden and risks

The risks associated with this study are low. All insole concepts are commonly used in clinical practice for diabetic patients. There is no known risk of in-shoe plantar pressure measurements. Patients will be measured on 3 occasions, participating in total 3 hours for the study.

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

- Diabetes mellitus
- Peripheral neuropathy
- Diabetic foot risk classification categories 2 and 3 (i.e. presence of peripheral vascular disease or foot deformity, or a history of foot ulceration).
- Possession of or prescription of semi-custom-made or fully custom-made footwear

Exclusion criteria

- Active ulceration
- Inability to walk at least 100m
- Amputation of more than 2 toes (not the hallux)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Top cover of an existing insole
Registration:	No

Ethics review

Approved WMO Date:	07-11-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL68629.018.19