Orthopaedic footwear concepts for the diabetic foot: effect on pressure relief and patient satisfaction

Published: 12-01-2015
Last updated: 22-04-2024

To assess the efficacy of different orthopaedic footwear concepts on the plantar pressure and patients satisfaction in diabetic patients at risk for foot ulceration

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON44324

Source
ToetsingOnline

Brief title
SHOECONCEPTS

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, Orthopedic footwear, Patient satisfaction, Plantar foot pressure

Outcome measures

Primary outcome

Peak plantar pressure

Secondary outcome

Patient satisfaction

Study description

Background summary

Different orthopaedic footwear design concepts have been developed over the last years with the goal to offload the plantar foot of diabetic patients with peripheral neuropathy who require special footwear to protect the foot against ulceration. Being fundamentally different in the approach to how the footwear is designed and evaluated, these footwear 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 orthopaedic footwear concepts on the plantar pressure and patients satisfaction in diabetic patients at risk for foot ulceration

Study design

Cross-sectional study design

Study burden and risks

The risks associated with this study are low. All footwear concepts studied have been part of previous studies and/or are commonly used in clinical footwear practice for diabetic patients. There is no known risk of in-shoe

plantar pressure measurement. Patients will be measured on 3 occasions, participating in total 4 hours for the study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

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
- Foot deformity that in terms of shoe fit does not allow the use of semi-custom-made footwear (i.e. midfoot Charcot foot, ankle deformity), as judged by the prescribing physician and shoe technician
- Amputation of more than 2 toes (not the hallux)

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):	29-05-2015
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Orthopedic footwear
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-01-2015
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	NL50344.018.14