

Offloading the diabetic foot

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20430

Bron

Nationaal Trial Register

Verkorte titel

Offloading the diabetic foot

Aandoening

diabetic foot ulcer
diabetische voet ulcus

Ondersteuning

Primaire sponsor: Dhr. E. Monteban
Ziekenhuisgroep Twente (ZGT)
Department of surgery
Zilvermeeuw 1
7609 PP Almelo, The Netherlands

Overige ondersteuning: sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Dynamic in-shoe plantar peak pressure.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Diabetes Mellitus (DM) is one of the most common chronic diseases. In these patients chronic non-healing ulcers of the foot are a significant problem. The first line of treatment consists of offloading these ulcers to reduce (peak) pressure at the ulcer location. Casting devices such as the total contact cast (TCC), bivalved TCC, or cast shoes are commonly used offloading treatment devices. However, the effect of these devices on the plantar peak pressure has not been directly investigated with between-device variability of the plantar sole controlled.

Objective of the study:

To assess the efficacy of a TCC, a BTCC and a cast shoe with similar plantar soles on offloading the previous ulcer location in people with DM and peripheral neuropathy.
Primary objective: a comparison between a TCC, BTCC and a cast shoe, all with a Solo vinyl cast sole.

Secondary objectives: a comparison between a cast shoe and a non-modelled cast shoe, both with a Solo vinyl cast sole, and a comparison between a cast shoe with a Solo vinyl cast sole and a cast shoe with a Cellona sole.

Study design:

Intervention study with a within-subject design, with one measurement session.

Study population:

Minimal 16 people with diabetes mellitus, peripheral neuropathy and a healed foot ulcer will be measured in all conditions.

Doel van het onderzoek

Casting devices such as the total contact cast (TCC), bivalved TCC, or cast shoes are commonly used offloading treatment devices. The effect of these devices on the plantar peak

pressure has not been directly investigated with between-device variability of the plantar sole controlled.

From this within-subject comparison, we can improve our understanding of the mechanisms used in offloading the diabetic foot, which may contribute to our understanding of the relation between offloading devices and healing of diabetic foot ulcers.

Onderzoeksopzet

During one measurement session the dynamic in-shoe plantar peak pressure and force-time integral will be measured with the Pedar-X system (Novel GmbH, Munich, Germany). The perceived walking comfort will be assessed after completion of data collection in each offloading device using a visual analogue scale (VAS) with outcome score ranging from 0 (very uncomfortable) to 10 (very comfortable).

Onderzoeksproduct en/of interventie

Total contact cast

Bivalved total contact cast

Cast shoe

Non-modelled cast shoe

Cast shoe with Cellona sole

Contactpersonen

Publiek

Ziekenhuisgroep Twente (ZGT) - Department of surgery

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Wetenschappelijk

Ziekenhuisgroep Twente (ZGT) - Department of surgery

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Almelo 7609 PP
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

People with diabetes who are at risk for plantar foot ulceration will be included. They must be 18 years or older, must have peripheral neuropathy and a healed plantar foot ulcer located at the hallux or metatarsal phalangeal joint (MTP) 1, 2, 3, 4 or 5 that was treated with a casting device. People must also present with one or more foot deformities, including claw/hammer toes, hallux valgus, hallux rigidus, prominent metatarsal heads, pes cavus, pes planus, rearfoot valgus and/or rearfoot varus.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

People will be excluded if they aren't able to walk a distance of 20 m repeatedly without walking aid. They will also be excluded if the previous ulcer location has been amputated, or they have Charcot deformity, equines foot deformity, treatment for serious medical conditions or injuries other than DM that may interfere with lower limb function (walking).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	16
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	25-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44038
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4890
NTR-old	NTR5137
CCMO	NL52480.044.15
OMON	NL-OMON44038

Resultaten

Samenvatting resultaten

nvt.