The effectiveness of using plantar pressure assessment and monitoring in prescription footwear to reduce re-ulceration rate in diabetic patients: A Randomized Controlled Trial.

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Therapeutic footwear of which adequate off-loading properties are guaranteed and monitored by dynamic plantar pressure assessment will result in a reduced plantar re-ulceration rate in diabetic patients with prior plantar foot ulceration compared to...

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

Samenvatting

ID

NL-OMON22571

Bron
NTR

Verkorte titel
DIAFOS trial

Aandoening

1. Diabetes;

2. Diabetic foot;

3. Neuropathy;

4. Footwear;

5. Plantar pressure.

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam, the Netherlands.
Overige ondersteuning: Academic Medical Center, Amsterdam, the Netherlands
Zon MW Clinical Fellowship (M. de Haart)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of patients with a plantar diabetic foot ulcer within an 18-month follow-up period.

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this multicenter randomized controlled trial is to assess the effectiveness of incorporating foot pressure measurements in the manufacturing of therapeutic footwear to guarantee adequate off-loading properties and as a method of monitoring the off-loading properties over time in preventing the recurrence of plantar foot ulcers in patients with diabetes mellitus.

Doel van het onderzoek

Therapeutic footwear of which adequate off-loading properties are guaranteed and monitored by dynamic plantar pressure assessment will result in a reduced plantar re-ulceration rate in diabetic patients with prior plantar foot ulceration compared to footwear manufactured and monitored according to current practice.

Onderzoeksopzet

Baseline assessment;

Entry visit (0 months);

Follow-up visits each 3 months for 18 months

Onderzoeksproduct en/of interventie

Therapeutic (orthopedic) footwear optimized and monitored using plantar pressure distribution measurement (Intervention group).

Therapeutic (orthopedic) footwear manufactured and monitored according to current clinical practice (Control group)

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >18 and <85 years old;

2. Diabetes mellitus type 1 or 2;

3. Loss of protective sensation due to peripheral neuropathy;

4. History of plantar foot ulceration within the last 18 months;

5. A new therapeutic footwear prescription.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active foot ulceration;

2. Amputation proximal to the metatarsal bones;

3. Severe illness that would make 18-months survival unlikely;

4. The use of walking aids that contribute to offloading the foot;

5. Parallel participation in another study that may influence the outcomes of this study;

6. Concomitant severe physical or mental conditions that limit the ability to follow instructions for the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1058
NTR-old	NTR1091
Ander register	: wordt doorgegeven
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A