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Effectiveness of podiatry to prevent foot ulcers in diabetic patients with polyneuropathy

Submission date	Recruitment status	[ ] Prospectively registered
21/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of preventive podiatric care versus treatment as usual to reduce the number of foot ulcers in diabetic patients with polyneuropathy: a randomised controlled trial

Acronym
Podoproof trial

Study objectives
The aim of the study was to determine whether preventive podiatric care reduces the number of foot ulcers or results in less severe ulcers in diabetic patients with polyneuropathy and no recent history of foot ulceration or severe foot deformities. Secondary endpoints for the study included markers of ulcer severity such as the number of hospitalisation days for a foot ulcer, the number of surgical or invasive vascular procedures and the number of days until an ulcer was healed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Academic Hospital Maastricht (azM)/Maastricht University Medical Centre (MUMC) approved on the 15th November 1996 (ref: AZM00230014/151196)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetic foot

Interventions
After randomisation, patients in the intervention group made an appointment with a participating local podiatrist within 2 weeks. These podiatrists (n = 20) were alumni of the School for Podiatry in Eindhoven, the Netherlands and were trained additionally for the purpose of this study. Subjects were instructed to visit the podiatrist for examination and treatment of their feet twice a year or more often as needed during the 3 year study period. Podiatric care included removal of callus, trimming nails, application of nail braces, prescribing insoles, orthotic toe

devices and other off-loading techniques as well as shoe adjustments. Moreover, education and advice about foot care and shoe wear were given at each visit. Clinical findings and applied therapeutic procedures were recorded.

In the control group extra podiatric consultations in case of (pre-)ulceration were allowed as well as treatment as usual.

Follow-up and care for their diabetes were continued as usual for both intervention and control group patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Development of a foot ulcer during the 3-year follow-up period
2. Number of ulcer related procedures in the 3-month period after the first detection of an ulcer

Secondary outcome measures
1. Severity of the ulcer
2. Healing time
3. Major interventions
4. Hospitalisation days related to ulceration

Measured at the onset of ulceration and after 3 month after onset of ulceration.

Overall study start date
09/09/1996

Completion date
01/05/2002

Eligibility

Key inclusion criteria
1. Patients aged over 18 years, either sex
2. Diabetes mellitus
3. Signs of peripheral polyneuropathy. Polyneuropathy is defined as absence of pressure sensation (10 gram Semmes Weinstein monofilament) and/or absence of the vibration perception sense (128 Hertz tuning fork).

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
281 patients per study group (562 in total)

Key exclusion criteria
1. Polyneuropathy not related to diabetes
2. Type 1 diabetes with a duration less than 10 years
3. An active foot ulcer or a healed ulcer in the past year
4. Severe peripheral arterial disease (ankle pressure less than 50 mmHg measured with a hand held Doppler)
5. Foot surgery or peripheral bypass surgery during the past year
6. Rheumatoid disease and renal replacement therapy
7. Patients should not have consulted a podiatrist in the past year

Date of first enrolment
09/09/1996

Date of final enrolment
01/05/2002

Locations

Countries of recruitment
Netherlands

Study participating centre
mgr.Witloxweg 22
Eindhoven
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Sponsor information

Organisation
University Maastricht (UM) (The Netherlands)

Sponsor details
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Sponsor type
University/education

Website
http://www.maastrichtuniversity.nl

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
University/education

Funder Name
Dutch Health Insurance Council (College van Zorgverzekeraars [CVZ]) (Netherlands)

Funder Name
Fontys University of Applied Sciences (Netherlands)

Funder Name
Maastricht University Medical Centre (Netherlands) - Division of Endocrinology Department of Internal Medicine

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration