

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

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Registration date 10/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Netherlands

5624JH

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration