The cost-effectiveness and cost-utility of monitoring foot temperature at home to prevent foot ulcer recurrence in patients with diabetes

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25946

Source
Nationaal Trial Register

Brief title
DIATEMP

Health condition

Diabetes mellitus, diabetic foot, foot ulcer

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam
Source(s) of monetary or material Support: ZonMw, The Netherlands organization for Health Research and Development.

Dutch Society for Podiatrists

ProVoet, branche organisation for pedicures

Intervention

Outcome measures

Primary outcome

- The proportion of patients with a foot ulcer recurrence on the plantar foot or medial and lateral forefoot surface during 18 months follow-up

- Cost (savings) per patient without a recurrent foot ulcer and per quality adjusted life year

Secondary outcome

- Costs of advanced therapy and ulcer treatment

- Adherence to at-home temperature monitoring

- In-shoe dynamic plantar pressure

- Barefoot dynamic plantar pressure

- Number of steps per day (daily ambulatory activity level)

- Footwear use

- Adverse events

- Quality of life

Study description

Background summary

In diabetic foot practice it proves difficult to prevent foot ulcer recurrence in patients with diabetes mellitus. Care providers and patients are in need of adjunctive ways to prevent foot ulcer recurrence. The home monitoring of foot temperatures, for early recognition and treatment of pre-signs of ulceration proves to be a promising approach. Despite that previous studies demonstrated the efficacy of the intervention, it is currently not (widely) applied in preventative foot care. Data that confirm earlier findings, data on cost-effectiveness and utility, and implementability are lacking.

This multicenter single-blinded randomized controlled trial with a patient follow-up of 18 months aims to assess the cost-effectiveness and cost-utility of at-home foot temperature monitoring to reduce the incidence of foot ulcer recurrence in patients with diabetes mellitus, in comparison to usual care.

Study objective

At-home infrared temperature monitoring of the foot in addition to usual care, is cost-effective and saves costs per quality adjusted life year gained in the prevention of foot ulcer recurrence in patients with diabetes, compared to usual care alone

Study design

1. 0 months: Baseline screening assessment: medical history and physical assessment, randomization, study instructions

2. Within 3 months after baseline: Biomechanical and activity assessment: barefoot and in-shoe pressure measurement, one-week activity and adherence monitoring.

3. Every three months: Proces monitoring for primary outcome and medical consumption, cost-data, and quality of life.

Intervention

The intervention consists of usual care added with at-home daily measurement of foot temperature at 6 predefined locations on both feet + max 1 or 2 locations based on ulcer history or pre-ulcer status, if different than predefined locations. If foot temperature is abnormal (i.e. >2.2 degrees celcius between same locations on both feet) on 2 consecutive days, the patient is instructed to contact the podiatrist, possibly for further foot diagnosis, and to reduce ambulatory activity until temperatures are normalized.

Usual care consists of: once every 1-3 months foot screening and/or foot care by a fot care specialist, patient education, and, if indicated, therapeutic footwear

Contacts

Public
Department of Rehabilitation
Academic Medical Center
University of Amsterdam
P.O. Box 22700

S.A. Bus
Amsterdam 1100 DE
The Netherlands
+31 20 5666905
Scientific
Department of Rehabilitation
Academic Medical Center

University of Amsterdam
P.O. Box 22700

S.A. Bus
Amsterdam 1100 DE
The Netherlands
+31 20 5666905

Eligibility criteria

Inclusion criteria

1. Diabetes mellitus type 1 or 2;

2. Age 18 or above;

3. Loss of protective sensation based on the presence of peripheral neuropathy;

4. Recent history of a foot ulcer or foot amputation (preceding 2 years)

5. Ability to provide informed consent

6. Ambulatory status

Exclusion criteria

1. Active foot ulceration or open amputation site

2. Active Charcot neuro-osteo arthropathy.

3. Active foot infection, based on criteria of the PEDIS classification

4. Amputation proximal to the Chopart joint in boot feet

5. Critical limb ischemia (according to PEDIS classification)

5. Severe illness that would make 18-months survival unlikely, based on the clinical judgement by the physician or podiatrist.

6. Concomitant severe physical or mental conditions that limit the ability to follow the instructions for the study, based on the clinical judgment by the physician or podiatrist.

7. Current use of home-monitoring of foot temperature.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	304
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-09-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44744
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5294
NTR-old	NTR5403
CCMO	NL52735.018.15
OMON	NL-OMON44744

Study results

Summary results
None