Cost-effectiveness and cost-utility of at-home infrared temperature monitoring in reducing the incidence of foot ulcer recurrence in patients with diabetes.

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To assess the cost-effectiveness and cost-utility of at-home foot temperature monitoring to reduce incidence of foot ulcer recurrence in patients with diabetes. Main research questions:1. What is the cost-effectiveness of enhanced therapy in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON44744

Source
ToetsingOnline

Brief title
DIATEMP

Condition

- Diabetic complications

Synonym
Diabetic foot, diabetic neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMW,NVVP;ProVoet

Intervention

Keyword: Cost-effectiveness, Diabetic foot, Prevention, Skin temperature

Outcome measures

Primary outcome

- Costs per patient without a foot ulcer and per quality adjusted life year.

- The proportion of patients with a foot ulcer recurrence during 18-month

follow-up.

Secondary outcome

- Costs of advanced therapy and ulcer treatment.

- Adherence to at-home foot temperature monitoring.

- Health-related quality of life.

Study description

Background summary

To prevent foot ulcer recurrence in diabetes, guidelines recommend protective pressure-relieving footwear, in addition to patient and family education, regular foot screening and preventative foot care. Despite these guidelines, risk of ulcer recurrence in patients after and episode of ulceration remains high, up to 40% in one year. Therefore, care providers and patients are in need of adjunctive ways to prevent ulcer recurrence. At-home monitoring of foot temperature shows promising results. Ulcers are preceded by increased local skin temperature due to inflammation and enzymatic autolysis of tissue as a result of being ambulatory. These increased temperatures can be easily assessed by patients using at-home monitoring of foot temperature. Timely identification of these areas allows the patient or care provider to take action to decrease the inflammation before an ulcer develops, for example by reducing ambulatory activity, and/or providing further offloading with footwear, orthoses or felted foam. Research in the US has shown that monitoring the foot temperature on a daily basis significantly reduced the risk ulcer recurrence. However, we do not know whether this applies to other settings and what the cost-effectiveness

and cost-utility is of the intervention. Furthermore, the approach is not yet implemented in foot care.

Study objective

To assess the cost-effectiveness and cost-utility of at-home foot temperature monitoring to reduce incidence of foot ulcer recurrence in patients with diabetes.

Main research questions:
1. What is the cost-effectiveness of enhanced therapy in preventing foot ulcer recurrence in diabetic patients?
2. What is the cost-utility of enhanced therapy in preventing foot ulcer recurrence in diabetic patients?
3. What is the effectiveness of enhanced therapy (i.e. usual care + at-home foot temperature monitoring) in comparison with usual care only on foot ulcer recurrence in diabeticp patients?
4. What is the adherence to at-home foot temperature monitoring in at-risk diabetic patients?

Study design

Multicenter single-blinded randomized controlled trial of two study amrs in a balanced design, with primary outcome assessors blinded to treatment allocation and patient follow-up of 18 months.

Intervention

the intervention is usual care added with at-home daily measurement of foot temperatures at 6 predefined locations on both feet. If foot temperature is increased on 2 consecutive days, the patient is instructed to contact the podiatrist, possibly for further foot diagnosis, and to reduce ambulatory activity with 50% until temperatures are normalized.

The intervention will be compared to usual care that generally consists of: therapeutic footwear, patient education, and once every 1-3 months foot screening and care by the podiatrist/ diabetes pedicure.

Study burden and risks

The burden is that patients in the intervention group are required to measure on a daily basis the skin temperature in their feet, as explaied above. The risks associated with the study are low. There is no known risk of at-home monitoring of the foot temperature.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Diabetes mellitus;
2. Age 18 or above;
3. Peripheral neuropathy;
4. Recent history of a foot ulcer or foot amputation, i.e. an ulcer has been present for at least 2 weeks and has healed within four years before randomization, or a diagnosis of midfoot or forefoot Charcot neuro-osteoarthropathy;
5. Ability to provide informed consent;
6. Ambulatory status (i.e. not permanently wheel-chair bound).
7. The patient is treated by a podiatrist or is willing to undergo treatment by a podiatrist from the study.

Exclusion criteria

1. Active foot ulceration or open amputation sites.
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 both feet.
5. Severe illness that would make 18-months survival unlikely, based on the clinical judgment by the physician
6. Concomitant severe physical or mental conditions that limit the ability to follow instructions for the study, based on the clinical judgment by the physician. This includes the inability to perform temperature measurements, without having a caretaker who can perform the temperature measurements.
7. Current use of home-monitoring of foot temperature.
8. Critical limb ischemia, based on criteria of the PEDIS classification

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2015
Enrollment:	304
Type:	Actual

Medical products/devices used

Generic name:	Infrared thermometer (TempTouchPlus)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25946
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52735.018.15
OMON	NL-OMON25946