Development of an intelligent telemedicine monitoring system for early detection of ulceration in diabetic feet

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON35774

Source
ToetsingOnline

Brief title
Early detection of ulceration in diabetic feet

Condition

- Diabetic complications

Synonym
ulceration due to diabetes mellitus; wounds due to diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: ZonMw (projectnummer 40-00812-98-09031)

Intervention

Keyword: diabetic feet, home monitoring, telemedicine, ulceration

Outcome measures

Primary outcome

- Proof of principle of the combination of modalities and software that can

accurately predict (pre-signs of) ulceration in diabetic feet.

Secondary outcome

- Collection of data from hyperspectral, photometric and thermal measurements,

as well as live assessments, to investigate modalities and develop software for

the proof of principle that is the main study parameter

Study description

Background summary

Many patients with diabetes suffer from vascular and neurological complications in the lower extremities. These conditions significantly increase the risk of developing foot ulcers, which in turn may lead to foot infection, and eventually to amputation of (part of) the foot or the lower leg and a loss in health-related quality of life.
Foot ulcers may be prevented by early detection of (pre-signs of) ulceration. Therefore, frequent examination of the feet is needed. However, self-examination is difficult or impossible due to consequences of the diabetes. Frequent examination by health care professionals is costly and not feasible.
Regular screening with an automated device, situated at a patient*s home and capable of warning health professionals when necessary, may reduce ulceration, and thereby improve patient*s autonomy and health-related quality of life.

Study objective

The ultimate objective is to develop an intelligent telemedicine monitoring system for early detection of (pre-signs of) ulceration in diabetic feet. The aim of the current project is to come up with a proof of principle of the

modalities needed to built such a system.

Study design

Observational study.

Study burden and risks

Only a light burden is put on patients by participating in this study. Measurements take 20 minutes and will be taken before a regular visit to the diabetic foot outpatient clinic. The measurements do not interfere with regular treatment. There are no known risks for the patients, as this is an observational study where only data from hyperspectral, photometric and thermal measurements of the patient*s feet will be collected with certified and safe measuring instruments. There are no direct benefits for the patients in participation. It is essential to perform this study in patients with diabetes, as the intelligent telemedicine monitoring system will be developed specifically for these patients.

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

- diabetes mellitus
- aged 18 years or more
- diagnosed with one of the following foot problems as a consequence of diabetes:
-- ulcer
-- callus
-- red skin
-- higher temperature on the skin of the foot
-- fissure
-- blister
-- crackle skin

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2011
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	30-08-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	03-07-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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: 27099
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL36061.044.11
OMON	NL-OMON27099