# Vincent50- Development of a system for the scanning of the diabetic foot in the home-environment- a pilot study

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The general aim of this pilot study is to assess the feasibility of using the Vincent 50 foot scanner for the acquisition, diagnosis, and referral of foot problems in the home environment in diabetic patients at high risk of ulceration.Specific aims...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Diabetic complications |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON29898

**Source**
ToetsingOnline

**Brief title**
Vincent50- diabetic foot scanner

### Condition

- Diabetic complications
- Peripheral neuropathies

**Synonym**
Diabetes, Diabetes Mellitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Ziekenhuisgroep Twente
**Source(s) of monetary or material Support:** Euregio subsidie

## Intervention

**Keyword:** diabetic foot, digital scanning, home-environment, telemedicine

## Outcome measures

### Primary outcome

The feasibility using the Vincent50 foot scanner in the home environment

### Secondary outcome

- Validity and reproducibility;

- Patient satisfaction;

- Patient compliance;

- Patient quality of life;

- Percentage of high-quality photographs that the clinician finds suitable for

assessment;

- Time needed for referral;

- Percentage of justified referrals;

- Total cost for using the Vincent50 foot scanner.

# Study description

### Background summary

Foot problems continue to be a significant problem globally in patients with diabetes mellitus. Chronic non-healing ulcers of the lower extremity are a significant problem in patients with diabetes mellitus. Among persons with diabetes, approximately 15% will develop a foot ulcer during their lifetime. The yearly incidence rate of ulceration in the overall diabetic population is 2.2% and 5.0 to 7.5% in diabetic patients with peripheral neuropathy. Foot ulcers precede 85% of all non-traumatic lower limb amputations, and half of all non-traumatic lower limb amputations in the United States are performed in persons with diabetes. Once amputation has occurred, statistics indicate a 33% to 42% morbidity rate for the contra-lateral limb within 1 to 3 years and 50%

tot 58% will suffer contra-lateral amputation within 3 to 5 years. Limb amputation in patients with diabetes is associated with an increased risk for further amputation, which has a 5-year mortality rate of 39% to 68%. The economic burden of diabetic foot problems is also substantial. Health care costs related to diabetic foot problems is the largest of all complications of diabetes. These statistics have led the World Health Organization and the International Diabetes Federation Declaration of St. Vincent in 1989 to call for a 50% reduction in foot amputation in Europe within 5 years.

**Study objective**

The general aim of this pilot study is to assess the feasibility of using the Vincent 50 foot scanner for the acquisition, diagnosis, and referral of foot problems in the home environment in diabetic patients at high risk of ulceration.

Specific aims are to:
1. Evaluate the validity and reproducibility of the Vincent50 foot scanner;
2. Evaluate the usability of the Vincent50 foot scanner in the home environment;
3. Evaluate the quality of pictures of the foot taken in the home-environment;
4. Recognize foot problems on the plantar surface at an early stage with using the Vincent50 foot scanner;
5. Evaluate patient satisfaction and quality of life with using the Vincent50 foot scanner in the home environment;
6. Establish a quick referral of patients to clinical care in case foot problems in the home environment occur.

**Study design**

This study is a pilot study in which the feasibility of using the Vincet50 foot scanner in the home environment will be tested in a total 60 patients. Each patient will be followed for a period of 3 months. Three times a week (Monday, Wednesday and Friday) both feet will be scanned. This image will be sent electronically to the call-center for evaluation by a trained physician.

**Study burden and risks**

The first visit (screening) will take about 45 minutes. During this visit a non-invasive vascular and neurologic test of the lower extremity will take place. In addition, blood will be taken from the patient and two quality of life scales will be filled in, the Rand36 and the EQ-5D. When patients fulfill the in- and exclusion criteria, the Vincent50 foot scanner will be installed at home, which will take about 45 minutes. The patient will be asked to scan their feet three times a week (Monday, Wednesday and Friday) for a period of three months. The scanprocedure will last for about 5 minutes. The final visit will take place at three months follow-up at the Twenteborg Hospital. Patients will

be asked to fill in the quality of life questionnaires and the self-developed usability questionnaire.

# Contacts

**Public**
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**Scientific**
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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, type 1 or 2
2. Age >18 years old
3. Highest risk for plantar ulceration:
- Peripheral sensory neuropathy and
- Healed plantar pressure ulcer in the last 6 months and
- Foot deformity present
4. Ability and willingness to cooperate with the requirements of the study:
- Have home telephone

- 3-month availability for the study
- Conform to the protocol (i.e. receive standard care and make use of the foot scanner at the listed frequencies)

### Exclusion criteria

1. Amputation at a level beyond the toes in either foot
2. Inability to follow the instructions for scanning of the foot due to physical, visual, or mental conditions
3. Intention to move outside of study area resulting in a change of hospital for foot care
4. Intention to spend more than one week from home (e.g. vacation)
5. Dependent in activities of daily living (ADL).
6. Parallel participation in another diabetic foot trial
7. Physical or mental conditions of which the patients* own physician feels they are, in the best interest of the patient, exclusion for participation.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-02-2007 |
| Enrollment: | 32 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Registration: | No |

# Ethics review

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|---|---|
| Approved WMO Date: | 06-09-2006 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL12796.042.06 |