Huidtemperatuur metingen bij de diabetische voet. Een observatie onderzoek naar de veranderingen van huidtemperatuur gedurende de dag

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON26082

Source
NTR

Brief title
skin temperature changes in the diabetic foot

Health condition

Diabetic foot ulcer
Home monitoring
Skin temperature

Diabetische voet ulcer
Thuis monitoring
Huidtemperatuur

Sponsors and support

Primary sponsor: Dr. J.J. van Netten
Source(s) of monetary or material Support: Ziekenhuisgroep Twente (ZGT) Department of surgery.

Saxion Hogeschool Enschede

Academie gezondheidszorg, opleiding podotherapie.

Intervention

Outcome measures

Primary outcome

To investigate changes during the day of the difference in skin temperature between the six contralateral spots in the feet of people with diabetes

Secondary outcome

Activity, body temperature and environmental temperature

Study description

Background summary

Background of the study:

For the prevention of diabetic foot ulceration, evidence exists to support the use of home-monitoring of foot skin temperature by means of a hand-held infrared skin thermometer. However, the construct validity of skin temperature measurements is unknown. Factors such as time of day, activity, body temperature and environmental temperature may influence skin temperature changes and could lead to false positive or false negative results if applied as home-monitoring instrument. Increased knowledge is important for the optimization of the measurement procedure and for using temperature measurements as a home screening tooi by patients with diabetes.

Objective of the study:

This pilot study intends to describe the skin temperature changes of the foot in patients with diabetes during the day. The secondary objectives are to describe the relationship with ambulatory activity, body temperature, and environmental temperature.

Study design:

Prospective observational pilot study.

Study population:

Twenty patients with Diabetes Mellitus type 1 and 2, classified as Simms' 1 or 2, above 18 years of age. Patients with clinical signs of infection, ulceration, major amputation, fever or critical ischemia are excluded.

Primary study parameters/outcome of the study:

Skin temperature differenee between six spots of the foot of patients with diabetes during four moments the day.

Secundary study parameters/outcome of the study (if applicable):

Activity, body temperature and environmental temperature

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
After agreeing to participate, participants visit the outpatient clinic onee. During this appointment, participants will be provided with the devices and a diary to measure the temperature at home.

The participants monitor the skin temperature of their feet four times a day for the period of one week. After this week, a staff member of the research team will visit the patient at home to evaluate the process and retrieve

Study objective

For the prevention of diabetic foot ulceration, evidence exists to support the use of home-monitoring of foot skin temperature by means of a hand-held infrared skin thermometer. However, the construct validity of skin temperature measurements is unknown. Factors such as time of day, activity, body temperature and environmental temperature may influence skin temperature changes and could lead to false positive or false negative results if applied as home-monitoring instrument. Increased knowledge is important for the optimization of the measurement procedure and for using temperature measurements as a home screening tooi by patients with diabetes.

This pilot study intends to describe the skin temperature changes of the foot in patients with diabetes during the day. The secondary objectives are to describe the relationship with ambulatory activity, body temperature, and environmental temperature.

Study design

Participants will be asked to measure the temperature of both feet, bodytemperature, environmental temperature and activity four times a day for the period of six days; the first time just after the participant wakes up, the second time between 11.00 and 13.00, the third time between 17.00-19.00 and the final time just before the participant goes to sleep. Data are to be recored in a diary.

Intervention

This pilot study intends to describe the skin temperature changes of the foot in twenty patients with diabetes during the day. The aim of the study is to gain knowledge about skintemperature changes of the feet during the day. Therefore the skintemperature is observed during dailly activities without an intervention.

Contacts

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Eligibility criteria

Inclusion criteria

- Type 1 or 2 diabetes

- Simms' classification 1 or 2

- No ulcer on the feet or legs

- No major amputation

- Aged 18 years or older

- Body temperature below 38°C

- No clinical signs of foot Infection.

- Able to use the thermometer and equipment

Exclusion criteria

Critical ischemia, defined as an ankle brachial index < 0.6 or toe pressure < 30 mmHg

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5077
NTR-old	NTR5209
Other	ABR : 53105

Study results