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

Gepubliceerd: 01-05-2015 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON26082

Bron
NTR

Verkorte titel
skin temperature changes in the diabetic foot

Aandoening

Diabetic foot ulcer
Home monitoring
Skin temperature

Diabetische voet ulcer
Thuis monitoring
Huidtemperatuur

Ondersteuning

Primaire sponsor: Dr. J.J. van Netten
Overige ondersteuning: Ziekenhuisgroep Twente (ZGT)

Department of surgery.

Saxion Hogeschool Enschede
Academie gezondheidszorg, opleiding podotherapie.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5077
NTR-old	NTR5209
Ander register	ABR : 53105

Resultaten