# Non-contact heat evoked vasomotor response in healthy subjects

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To study the quantitative and qualitative relationship between a heat stimulus and the vasomotor response in healthy subjects and to determine the feasibility of this measurement setup for patients.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39257

**Source**
ToetsingOnline

**Brief title**
Vasomotor response

### Condition

- Other condition
- Peripheral neuropathies

**Synonym**
small fiber neuropathy, small nerve fiber disease

**Health condition**

thermoregulatie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** STW10730

## Intervention

**Keyword:** small fiber neuropathy, thermoregulation, vasomotor response

## Outcome measures

### Primary outcome

The main study parameter is the reliability and repeatability of the heat

evoked vasomotor response, which will be measured using 1) Pulse Transit Time

(PTT), 2) Laser Doppler, and 3) videothermography.

### Secondary outcome

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# Study description

### Background summary

Small nerve fiber neuropathy is a common disorder, characterized by dysfunction of the small nerve fibers often leading to neuropathic pain. Neuropathic pain has a large socio-economic impact and an enormous influence on quality of life. The gold standard for diagnosing small fiber dysfunction is skin biopsy, which is invasive, labor intensive and had limited accuracy. Therefore there is clinical demand for a simple non-invasive test to objectively quantify small fiber dysfunction. Such a test would enable early diagnosis and allow early treatment to potentially delay chronification.
Besides the pain system, small fiber dysfunction also affects the local blood flow system. Skin blood flow is modulated by thermoregulation and responds to local changes in temperature. Local warming (e.g. on a hot summer day, during physical exercise, or by an external heat source) induces vasodilation and increases skin blood flow. The heat induced change in blood flow (vasomotor response) can be assessed with several standard techniques, e.g. laser Doppler and videothermography. Application of temperature stimuli together with the measurements of blood flow enable quantification of the vasomotor response and thereby provide information on the thermoregulatory system. However, an

effective method for applying temperature stimuli in combination with those measurement techniques is lacking.

### Study objective

To study the quantitative and qualitative relationship between a heat stimulus and the vasomotor response in healthy subjects and to determine the feasibility of this measurement setup for patients.

### Study design

A prospective, observational, single centre study conducted in the Erasmus Medical Centre.

### Intervention

A sequence of safe non-contact infrared heat pulses applied to the skin by an external heat source to induce vasomotor response.

### Study burden and risks

The measurements are without risk, they are all non-invasive. Application of the heat stimulus imposes only a minor risk because we stay within the EU safety regulations; risk of skin damage is negligible.

## 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

Healthy adult volunteers, aged 18-35 years or 50-60 years old.

### Exclusion criteria

Cardiovascular disease (e.g. hypertension, diabetes mellitus) or other diseases which affect vasomotor functioning.
Injuries to site of measurement

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2010 |
| Enrollment: | 50 |
| Type: | Anticipated |

# Ethics review

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| Approved WMO Date: | 23-12-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 15-03-2013 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL33823.078.10 |