# A single-centre prospective observational study into development of microcirculatory alterations and response to therapy in adult critically ill patients

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The primary objective of this study is to identify in what manner micro- and macro hemodynamic parameters responds to critical illness and therapy, and to determine how this interaction is related to different states of organ dysfunction (heart,...

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

## Summary

### ID

NL-OMON40618

**Source**
ToetsingOnline

**Brief title**
Microcirculatory response to therapy

### Condition

- Other condition
- Heart failures
- Cardiac therapeutic procedures

**Synonym**
cardiovascular collapse and low blood flow to the tissues

**Health condition**

circulatory shock and tissue hypoperfusion

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** circulatory shock, microcirculation, organ dysfunction, sepsis

## Outcome measures

### Primary outcome

Standard Operating Procedure for measurement of Microcirculatory perfusion

(cutaneous / mucosal / sublingual tissues): vessel density parameters,

microvascular flow index, and flow heterogeneity.

### Secondary outcome

not applicable

# Study description

### Background summary

Rationale: Assessment of the microcirculation is considered important adjunct measurements to conventional systemic hemodynamic monitoring, such as arterial blood pressure, heart rate, cardiac output and its determinants. Microcirculation assessment is possible using sidestream dark field imaging. However, its use has several limitations that have hampered the introduction of this mode of hemodynamic diagnosis into routine clinical practice. A new technologically advanced version of hand held microscopes (CytoCam, Braedius Medical, Naarden the Netherlands) based on Incident Dark Field (IDF) imaging with improved ease and speed of measurement and higher optical resolution has been recently introduced allowing more vessels to be observed with larger detail. The device is based on a computer controlled large resolution imaging sensor and allows instant quantification of images to provide the needed

microcirculatory parameters directly at the bedside. This advance now offers the opportunity of introducing the clinical evaluation of the microcirculation into routine clinical use at the bedside, allowing sequential measurements to follow for the first time the evolution of microcirculatory alterations in disease and therapy.

### Study objective

The primary objective of this study is to identify in what manner micro- and macro hemodynamic parameters responds to critical illness and therapy, and to determine how this interaction is related to different states of organ dysfunction (heart, kidney and lung) and to the outcome. The secondary objective is to establish whether improved microcirculatory parameter as a consequence of standard therapy is associated with an improvement in organ function as assessed by SOFA score. Given that IDF CytoCam is a new technologically advanced version of hand held microscopes not yet performed in humans, a group of patients after elective surgery and a group of healthy volunteers will be used as control healthy microcirculation.

### Study design

single-center prospective observational study

### Study burden and risks

Microcirculation assessment is a noninvasive procedure, and there are no risks associated with this monitoring device. The risks associated with participation can be considered negligible and the burden can be considered minimal.

## 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

In order to be eligible to participate in this study, a subject must be adult (> 18 yrs-old) and meet the description of the study groups stated in the section 4.2, page 13 in the protocol.

## Exclusion criteria

Moribund

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Diagnostic

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 15-01-2014 |

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|---|---|
| Enrollment: | 168 |
| Type: | Anticipated |

## Ethics review

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|---|---|
| Approved WMO Date: | 24-01-2014 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 16-01-2015 |
| 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 | NL45915.078.13 |