# Microcirculatory alterations in septic patients admitted to the intensive care

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

## Summary

### ID

NL-OMON34976

**Source**
ToetsingOnline

**Brief title**
Microcirculatory alterations in sepsis

### Condition

- Other condition

**Synonym**
septic shock, severe sepsis

**Health condition**

ernstige sepsis en septische shock

**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:** Microcirculation, Peripheral perfusion, Sepsis

## Outcome measures

### Primary outcome

The primary study parameter is the peripheral perfusion measured at the skin of

the extremities and the sublingual microcirulatory perfusion.

### Secondary outcome

not applicable

# Study description

### Background summary

In patients admitted to the intensive care unit with severe sepsis, microcirculatory alterations are frequently observed. These microcirculatory alterations are associated with a poor prognosis especially when these alterations do not improve in time. There are several ways to measure microcirculatory perfusion, peripherally on the skin of the extremities or in a more central compartment i.e. sublingually. It remains unclear which of these parameters characterizes the microcirculatory perfusion of the septic patient . Additionally it is not known which of the perfusion parameters are related to outcome.

### Study objective

The aim of the study is to observe which of the microcirculatory parameters characterizes the septic patients and to investigate which of these alterations are related to mortality and organfailure. Additionally the changes over time, the relationship with systemic hemodynamic parameters and the interrelationship between the several parameters of microcirculatory perfusion will be studied.

### Study design

The study will be carried out on the Intensive Care of the Erasmus Medical Center and will be carried out as a single center observational study.

**Study burden and risks**

The measurements of peripheral perfusion and sublingual microcirculation will not involve risks for the subject. The methods to measure peripheral perfusion are based on light with harmless wavelengths. The measurement probes will only slightly make contact with the skin and the sublingual area of the subject.
In the future patients could benefit from the results, by optimizing the treatment based on individual parameters of microcirculatory perfusion.

# 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

Patients admitted to the intensive care with organ dysfunction or circulatory failure due to severe sepsis or septic shock. Age > 18 years.

### Exclusion criteria

Severe vascular pathology. Circumstances making it impossible to perform sublingual measurements, like bleeding of the oral cavity

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-05-2010 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 29-04-2010 |
| Application type: | First submission |
| 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 | NL30450.078.10 |