# Microcirculatory perfusion as measured by sublingual Side Stream Darkfield (SDF) imaging and Near Infrared Spectroscopy (NIRS) in mild therapeutic hypothermia (TH) and non-TH patients

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Over the last decades, attempts have been made to identify perfusion abnormalities at the organ level, for example with tonometry, lactate levels, near infrared spectroscopy (NIRS) and microdialysis. Direct visualization of the microcirculation with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

# Summary

### ID

NL-OMON38328

**Source** ToetsingOnline

**Brief title** Microcirculation in mild therapeutic hypothermia and non TH patients

# Condition

Other condition

Synonym

microcirculation, rescucitation

#### Health condition

microcirculatie bij reanimatie patienten

1 - Microcirculatory perfusion as measured by sublingual Side Stream Darkfield (SDF) ... 26-05-2025

#### **Research involving**

Human

### **Sponsors and support**

Primary sponsor: Medisch Centrum Leeuwarden Source(s) of monetary or material Support: Stichting Onderzoek Intensive Care Leeuwarden

#### Intervention

Keyword: microcirculatory perfusion, NIRS, SDF imaging, therapeutic hypothermia

### **Outcome measures**

#### **Primary outcome**

Primary outcome: MFI sublingual (SDF)

#### Secondary outcome

Secondary outcome: RincStO2 (NIRS), fluid balance after 24 hours, inotropes and

vasopressor dose, cardiac index, lactate, SvO2

# **Study description**

#### **Background summary**

Treatment with mild therapeutic hypothermia (TH) is associated with an assumed protective decrease of oxygen consumption under conditions of potentially inadequate oxygen delivery.

In this context, during TH adequate oxygen delivery as measured by S(c)vO2 has been reported, despite lower cardiac output, caused by relative bradycardia and lower stroke volume (1).

However, such macrohemodynamic variables may not reflect potential distributive microcirculatory alterations, both as a result of the inflammatory response caused by ischemia-reperfusion and by TH as a therapeutic entity.

A recent retrospective observational study in our own ICU in 62 patients after cardiac arrest and invasive hemodynamic monitoring (2), using pulmonary artery catheter (Vigilance) or arterial pulse contour analysis (PiCCO), revealed an increase in Cardiac index (CI) and S(c)vO2 during steady state hypothermia of 33\*C. CI rose from 2.3 L/m2 (1.9-3.0) to 2.7 (2.3-3.8), p=0.002 and S(c)vO2 increased from 77% (70-84) to 80 (75-85), p= 0.12 respectively (1). At the same time, arterial lactate levels at the beginning of steady state hypothermia were 2.1 (1.2-3.7) mmol/L and increased significantly to 3.4 (1.8-4.9) at the end of hypothermia (p= 0.000).

This raised the question whether TH itself might induce distributive microcirculatory failure. Alternative explanations for the observed combination of increase of lactate, and S(c)vO2/CI may be the inability to prevent microcirculatory failure despite adequate treatment with TH or direct effects of treatment aimed at optimizing hemodynamics.

### Study objective

Over the last decades, attempts have been made to identify perfusion abnormalities at the organ level, for example with tonometry, lactate levels, near infrared spectroscopy (NIRS) and microdialysis.

Direct visualization of the microcirculation with orthogonal polarizing spectral (OPS) imaging and its technical successor, side stream darkfield (SDF) imaging (3) - with the ability to quantify abnormalities both at the bedside and off-line has recently elucidated the distributive nature of microcirculatory flow abnormalities and its correlation with prognosis in sepsis and heart failure. Recent studies indicate that distributive alterations in the microcirculation of patients not only can be observed, but are also associated with outcome. The importance of direct visualization of the microcirculation is further stressed by studies that do not observe a clear association between systemic hemodynamic variables and microcirculatory parameters, suggesting that indeed the microcirculatory compartment plays a crucial role in the development of organ failure.

SDF has been used to reveal microcirculatory blood flow changes both sublingually (human) and in the cerebral vascular compartment (animal studies) during cardiac arrest and CPR; the observed abnormalities were predictive of outcome. (4)

Changes in muscle tissue oxygenation (StO2) after an ischemic challenge using near-infrared spectroscopy (NIRS) were found in patients with sepsis and in particular in septic shock (5). NIRS may be a useful technique to monitor microcirculatory changes in patients after cardiac arrest.

### Study design

To investigate the prevalence of microcirculatory dysfunction, SDF measurements of the sublingual microcirculation will be performed in all patients recruited for the TTM trial in the Medical Center Leeuwarden. The technique consists of a handheld microscope with a light guide and a disposable sterile lens at the tip. This light guide is placed on tissue (e.g. sublingual mucosa), and light with a wavelength within the absorption spectrum of hemoglobin is emitted. Side illumination is used at the area under investigation: the lens is optically isolated from the outer ring with LEDs, thereby preventing the influence of surface reflections (fig) In this way the perfusion (e.g. flow) as well as the density of the functional capillaries can be determined at the bed side.

#### Study burden and risks

# Contacts

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Public Medisch Centrum Leeuwarden

Henri Dunantweg 2 Leeuwarden 8901 BR NL **Scientific** Medisch Centrum Leeuwarden

Henri Dunantweg 2 Leeuwarden 8901 BR NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

inclusion TTM trial >18 years informed consent

# **Exclusion criteria**

no informed consent

# Study design

# Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	22
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	27-01-2011
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO	
Date:	10-09-2012
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

5 - Microcirculatory perfusion as measured by sublingual Side Stream Darkfield (SDF)  $\dots$  26-05-2025

# **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 CCMO **ID** NL34920.099.10