# Measuring limb perfusion with Near Infrared Spectroscopy (NIRS), Cellular Oxygen METabolism (COMET) and Dynamic Light Scattering (DLS) during Minimally Invasive Cardiac Surgery (MICS)

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Determine the difference in mitoPO2 in between the cannulated and non-cannulated and the difference in DLS red blood cell velocity (RBV) between the two legs, in patients undergoing a cardiopulmonary bypass (CPB) MICS with standard cannulation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

# Summary

#### ID

NL-OMON54306

**Source** ToetsingOnline

Brief title LP-MICS

### Condition

- Cardiac therapeutic procedures
- Vascular injuries

Synonym

Leg ischemia / Limb 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: COMET, DLS, Limb Perfusion, Minimal invasieve cardiac surgery

#### **Outcome measures**

#### **Primary outcome**

During surgery the tissue oxygen saturation, mitoPO2 and microcirculatory blood velocity will be measured continuously in the cannulated and non-cannulated limb.

The main study parameter is the difference in mitoPO2 levels between the cannulated and non-cannulated leg and the difference in RBV measurements between these limbs, during cannulation, five minutes before end of CPB.

#### Secondary outcome

- Difference in mitoPO2 levels between the cannulated and non-cannulated leg during the other flow alternating moments (before cannulation, start CPB, extra leg canula in case of ischaemia, end of CPB and after decannulation).

- Difference in RBV measurements between the cannulated and non-cannulated leg during the other flow alternating moments (before cannulation, start CPB, extra leg canula in case of ischaemia, end of CPB and after decannulation).

- Difference in response time of mitoPO2 and StO2.

- Difference in response time of RBV and StO2.

- Temperature (C) difference in both legs, as measured with the COMET probe.

- Mean difference in flow as measured by the DLS sensor at the tube of the CPB

pump and the flow of the CPB system

# **Study description**

#### **Background summary**

Minimally Invasive Cardiac Surgery (MICS) is a minimal access method for cardiac surgery requiring cannulation of the femoral vein and artery instead of central cannulation for cardiopulmonary bypass. The arterial cannula frequently compromises the perfusion (decreased cellular oxygenation) of the cannulated limb, requiring an additional distal leg cannula.

The current \*golden standard\* for detecting cellular ischemia is near-infrared-based tissue oxygen saturation measurement (StO2, ForeSight Elite) of both legs. A decline of 20% of the baseline StO2 or StO2 measurements below 50% is defined as critical. The recently introduced Cellular Oxygen METabolism (COMET) monitor (Photonics Healthcare) measures cutaneous mitochondrial oxygen tension (mitoPO2) and oxygen consumption (MitoVO2) and can detect cellular ischaemia very early. Moreover, dynamic light scattering (DLS) sensors (Elfi-Tech Ltd.) enable measurement of the microcirculatory blood velocity in order to investigate limb perfusion and can detect a decrease in blood velocity. The hypothesis is that these two new techniques are able to detect ischemia in the cannulated leg more reliably and earlier than the currently available technique.

#### **Study objective**

Determine the difference in mitoPO2 in between the cannulated and non-cannulated and the difference in DLS red blood cell velocity (RBV) between the two legs, in patients undergoing a cardiopulmonary bypass (CPB) MICS with standard cannulation.

#### Study design

Single centre, blinded, observational cohort study.

#### Study burden and risks

The intracellular oxygen measurement, using NIRS, is a non-invasive measurement technique and does not lead to deviations from standard protocols. A discomfort for the patient could be the aminolevulinic acid (ALA) containing-plaster, in order to make the skin sensitive for light and causing transient irritation of the skin, which is needed for the COMET measurement. This plaster is applied on

the skin on the evening before the scheduled surgery. The DLS sensor contains a class 1 laser source and is safe for the human retina. The sensor will be attached to the skin using double-sided adhesives, custom adhesive rings and/or commercially available adhesive rings that are used for regular care transcutaneous blood gas monitoring. Overall, the study comes with a negligible risk and the burden is very low.

# 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**

- 18 years or older

- Acceptable proficiency of the Dutch or English language
- ASA 2-4

- Minimally invasive cardiac surgery requiring cardiopulmonary bypass

### **Exclusion criteria**

- Absence of written informed consent
- Presence of mitochondrial disease
- Pregnancy/lactation
- Emergency surgery
- Patients with skin laesions on the lower extremities which impede

measurements

# Study design

## Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2022
Enrollment:	46
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	07-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	13-12-2022

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-03-2023
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
ССМО	NL76108.078.21

# **Study results**

Date completed:	02-05-2023
Actual enrolment:	43