the MICCS study: the complex relation between the microcirculation and macrocirculation in patients after cardiothoracic surgery with and without circulatory shock

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In this study, we aim to investigate the postoperative time course of microcirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock. Secondary objectives:* To study the postoperative time…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON51419

Source
ToetsingOnline

Brief title
The MICCS study

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Decreased and nonspecific blood pressure disorders and shock

Synonym
cardiogenic and distributive shock, Circulatory shock

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiothoracic surgery, Circulatory shock, Microcirculation, Sublingual

Outcome measures

Primary outcome

Primary study outcome

The primary outcome is the time course of microcirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock.

Secondary outcome

Secondary study outcomes include:

• The time course of microcirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock

• The coherence between the maicrocirculation and microcirculation in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock. Coherence meaning whether changes in microcirculatory parameters are congruent with (in the same direction of) expected changes in the microcirculation.

• The relationship between the microcirculation and vital organ (dys)function, particularly the need for vasopressors and/or inotropic therapy or duration of mechanical support.

• The association between microcirculation and clinical outcomes (i.e. acute

kidney injury, the need for continuous venovenous hemofiltration, length of

stay ICU and ICU mortality

Study description

Background summary

In patients after cardiothoracic surgery, changes in the microcirculation will occur. Causes of these changes in the microcirculation can be tissue trauma, activation of the inflammatory response and haemostatic system, anaesthesia, hypothermia and formation of micro-embolisms. An impaired microcirculation results in a decreased tissue oxygenation or even organ damage if a situation of low tissue oxygenations persists.
Monitoring on the Intensive Care Unit (ICU), is mainly focused on microcirculatory and macrocirculatory parameters, such as blood pressure, cardiac output and saturation. The hemodynamic coherence between the macrocirculation and the microcirculation is the condition under which resuscitation procedures aimed at correcting macrocirculatory parameters are also effective in correcting microcirculatory perfusion and cellular oxygenation. Different studies in patients with sepsis or septic shock show that a loss of hemodynamic coherence can occur. This means that during resuscitation, macrohemodynamic parameters improve to normal values while microcirculation is still altered, a condition that is associated with increased morbidity and mortality 3. This loss of coherence may also be present in patients after cardiothoracic surgery. Routinely measuring the microcirculation with the CytoCam may therefore be valuable in monitoring patients after cardiothoracic surgery.

Study objective

In this study, we aim to investigate the postoperative time course of microcirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock.

Secondary objectives:
* To study the postoperative time course of macrocirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock.
* To investigate the relationship (i.e. coherence) between microcirculatory parameters and macrocirculatory parameters in patients admitted to the ICU after cardiothoracic surgery with and without circulatory shock.

* To study the relationship between the microcirculation and vital organ (dys)function, particularly the need for vasopressors and/or inotropic therapy or duration of mechanical support.
* To study the relationship between postoperative microcirculatory parameters and clinical outcomes (i.e. acute kidney injury, the need for continuous veno-venous hemofiltration, length of stay ICU and ICU mortality).

Study design

Prospective single-centre cohort study.

Intervention

Included patients will undergo treatment after cardiothoracic surgery according to current clinical practice. Microcirculation measurement with the CytoCam will be performed as soon as possible after ICU admission (within 24 hours (T0)), then within 24 hours (T1) after admission to the ICU, and if possible >48 hours (T2) after T0. No delay of treatment will take place. Data collection, including circulatory, respiratory and inflammatory data, as well as blood samples and fluid balance, will occur at the same time as the microcirculatory measurements. Simultaneously with To, demographic data will be collected.

If a patient develops shock (a condition in which there is a lack of effective circulating volume resulting in insufficient tissue perfusion) or the need to receive mechanical support while on the ICU, microcirculation measurements will be measured according to the current Shock protocol of LUMC.

Study burden and risks

All devices used in this study are minimal-invasive, easy to use, and electrically safe. The use of the devices is risk-free. For the participating patients, there are no advantages or disadvantages to the study. The study is about gaining insight into the microcirculation in relation to the macrocirculation in cardiothoracic surgery patients, with or without circulatory shock. These results may contribute to the understanding and more effective treatment of circulatory shock after cardiothoracic surgery. The patient is measured a maximum of 3 times for several minutes. These measurements are completely painless and of short duration.

In conclusion, we believe that this is a valuable study for post cardiothoracic surgical patients, with almost no risks and some potential benefits for future patients. We therefore believe that this study is ethical.

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

- Age of patient is at least 18 years
- Patients are admitted to the ICU after cardiothoracic surgery

Exclusion criteria

- Patients who refuse to take part in the study
- Patients younger than 18 years
- Patients with maxillofacial trauma
- Patients known with tumor(s) in the mouth or throat area

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	CytoCam
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-10-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL81756.058.22