Evaluating the accuracy and reliability of sublingual micro-circulation measurements as an adjunct to fluid management in Cardiac Surgery patients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48275

Source
ToetsingOnline

Brief title
Sublingual micro-circulation measurements in Cardiac Surgery patients

Condition

- Myocardial disorders

Synonym
coronary atherosclerosis (coronary disease)

Research involving
Human

Sponsors and support

Primary sponsor: Select

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Fluid management, Micro-circulation, Sublingual

Outcome measures

Primary outcome

To determine how microcirculation is affected during fluid resuscitation and

de-escalation phase of fluid therapy

Secondary outcome

Not applicable.

Study description

Background summary

Open cardiac surgery leads to severe inflammation and is related with a wide range of micro- and macro-circulatory derangements which may correspond to reduced tissue oxygenation. Improvement of tissue oxygenation is important to decrease post-surgical morbidity and mortality. Fluid and/or vasopressor/inotrope therapies are used in order to restore tissue perfusion. Fluid administration is the first step in the resuscitation of perioperative patients displaying signs of impaired organ perfusion. Inadequate fluid therapy leads to hypovolemia and consequently inappropriate use of vasopressor therapy. Conversely, excessive fluid administration during the perioperative period leads to a positive cumulative fluid balance and is regarded as one of the most common clinical problems in post-intensive care unit (ICU) cardiac surgery patients. Fluid overload can cause several complications which result in a longer recovery period, increased length of hospital stay, increased morbidity and decreased quality of life after surgery. The volume of administered fluid is often excessive and no real end points for its administration are currently available. The *de-escalation phase* follows fluid administration and describes the event where fluid is removed from the patient. Several options are available, but the common methods are the use of diuretics and ultrafiltration if required.
Unfortunately, global macro-hemodynamic parameters like systemic blood pressure, heart rate and urine output may not reflect microcirculatory dysfunction. The microcirculation may remain deteriorated despite the global

hemodynamic parameters are improved. Direct visualization of the sublingual microcirculation with hand-held vital microscopy (HVM; Cytocam-IDF (Braedius Medical, Huizen the Netherland) may provide the clinician to monitor fluid therapy by potentially preventing the unnecessary and inappropriate administration of large volumes of fluids and monitor the success of de-escalation therapy thereby allowing more physiologically based approaches for the diagnosis and treatment of cardiac surgery patients.

Study objective

The primary aim of the study is to determine how microcirculation is affected at the bedside during fluid resuscitation and de-escalation phase of fluid therapy during surgery and in post-ICU cardiac surgery patients. The secondary aims of the study are to determine how the microcirculation changes in parallel with macro-circulation during these phases of fluid administration, to determine the usability of Nexfin® (BMEYE, Amsterdam, The Netherlands) for non-invasive cardiac output measurement and Bioimpedance (Body Composition Monitor (BCM), Fresenius Medical Care, Bad Homburg, Germany) for non-invasive measurement of tissue water and weight in association with macro-hemodynamic parameters such as blood pressure and oxygen saturation during fluid resuscitation and de-escalation phase of fluid therapy .

Study design

Observational cohort study.

Study burden and risks

There are no risks associated with the use of the Cytocam. The burden is minimal, the measurments are painless, patients do not need to come back to the hospital for extra examinations. They endure measurements at three different time points, each time it costs approximately 30 minutes to complete the measurements.

Contacts

Public
Select

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Scientific
Select

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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 referred to the Department of Cardiothoracic Surgery of the AMC for elective cardiac surgery
-Patients with no previous history of oral diseases or oral surgery
-Patients that signed an informed consent form
-Patients > 18 years

Exclusion criteria

-Patients with a previous history of oral disease or oral surgery, having maxillofacial trauma or ear nose throat tumors
-Patients that did not sign an informed consent form
-Patients < 18 years
- Moribund and pregnancy
- Inability to consent or having mental disorder
- Morbid obesity
- Chronic renal failure
- Existence of defibrillator
- Amputation of the extremities
- Skin defect or inflammation that effects the use BCM (bioimpedantie monitor)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-12-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL67880.018.18