A single-centre prospective observational study into development of microcirculatory alterations and response to therapy in adult critically ill patients

Published: 24-01-2014
Last updated: 24-04-2024

The primary objective of this study is to identify in what manner micro- and macro hemodynamic parameters responds to critical illness and therapy, and to determine how this interaction is related to different states of organ dysfunction (heart,...

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

Summary

ID

NL-OMON40618

Source
ToetsingOnline

Brief title
Microcirculatory response to therapy

Condition

- Other condition
- Heart failures
- Cardiac therapeutic procedures

Synonym
cardiovascular collapse and low blood flow to the tissues

Health condition

circulatory shock and tissue 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: circulatory shock, microcirculation, organ dysfunction, sepsis

Outcome measures

Primary outcome

Standard Operating Procedure for measurement of Microcirculatory perfusion

(cutaneous / mucosal / sublingual tissues): vessel density parameters,

microvascular flow index, and flow heterogeneity.

Secondary outcome

not applicable

Study description

Background summary

Rationale: Assessment of the microcirculation is considered important adjunct measurements to conventional systemic hemodynamic monitoring, such as arterial blood pressure, heart rate, cardiac output and its determinants. Microcirculation assessment is possible using sidestream dark field imaging. However, its use has several limitations that have hampered the introduction of this mode of hemodynamic diagnosis into routine clinical practice. A new technologically advanced version of hand held microscopes (CytoCam, Braedius Medical, Naarden the Netherlands) based on Incident Dark Field (IDF) imaging with improved ease and speed of measurement and higher optical resolution has been recently introduced allowing more vessels to be observed with larger detail. The device is based on a computer controlled large resolution imaging sensor and allows instant quantification of images to provide the needed

microcirculatory parameters directly at the bedside. This advance now offers the opportunity of introducing the clinical evaluation of the microcirculation into routine clinical use at the bedside, allowing sequential measurements to follow for the first time the evolution of microcirculatory alterations in disease and therapy.

Study objective

The primary objective of this study is to identify in what manner micro- and macro hemodynamic parameters responds to critical illness and therapy, and to determine how this interaction is related to different states of organ dysfunction (heart, kidney and lung) and to the outcome. The secondary objective is to establish whether improved microcirculatory parameter as a consequence of standard therapy is associated with an improvement in organ function as assessed by SOFA score. Given that IDF CytoCam is a new technologically advanced version of hand held microscopes not yet performed in humans, a group of patients after elective surgery and a group of healthy volunteers will be used as control healthy microcirculation.

Study design

single-center prospective observational study

Study burden and risks

Microcirculation assessment is a noninvasive procedure, and there are no risks associated with this monitoring device. The risks associated with participation can be considered negligible and the burden can be considered minimal.

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

In order to be eligible to participate in this study, a subject must be adult (> 18 yrs-old) and meet the description of the study groups stated in the section 4.2, page 13 in the protocol.

Exclusion criteria

Moribund

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2014

Enrollment:	168
Type:	Anticipated

Ethics review

Approved WMO Date:	24-01-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-01-2015
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
CCMO	NL45915.078.13