Routine Microcirculation Measurements in Intensive Care Unit Patients and Validation by PiCCO Technology. ROUMI-study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23604

Source
NTR

Brief title
ROUMI

Health condition

Patients with any type of shock in the ICU

Sponsors and support

Primary sponsor: Investigator initiated
Source(s) of monetary or material Support: Own ICU sources

Intervention

Outcome measures

Primary outcome

o To investigate the correlation of microcirculatory parameter MFI measured with Cytocam-

IDF with Cardiac Index measured using the trans-pulmonary hemodilution technique PiCCO

Secondary outcome

o To investigate the value and feasibility of routine monitoring of sublingual microcirculation as an early warning of clinical deterioration/improvement before the diagnosis can be made with laboratory, vital and hemodynamic parameters in critically ill patients.

Study description

Background summary

The fundamental aim of resuscitation of critically ill patients is to restore tissue perfusion and oxygenation. Systemic macro-hemodynamic parameters are conventionally used to assess and monitor resuscitation success in routine clinical practice, assuming that tissue perfusion and oxygenation recover parallel to systemic hemodynamic parameters. However, tissue perfusion and oxygenation may remain impaired despite correction of systemic circulatory parameters. This loss of association between the systemic and microcirculation is referred to as a loss of 'hemodynamic coherence. Direct visualization of sublingual microcirculation using hand-held video microscopes such as the Cytocam-IDF (Braedius Medical, Huizen the Netherland) imaging device can be used to identify such loss of hemodynamic coherence and may provide an opportunity to monitor resuscitation therapy and allows more physiologically based approaches for the diagnosis and treatment of intensive care patients. However, it has not been correlated with an invasive and gold standard hemodynamic monitoring tool such as PiCCO technology. PiCCO monitorization is one of the most common invasive technique used to assess systemic hemodynamic status in severe critically ill patients. However most clinical used and strongly evidence based parameters are still cardiac index and stroke volume index. Therefore, we especially sought to compare the microcirculatory parameters which indicates adequate tissue perfusion, MFI, TVD, PVD and PPV, to cardiac index (CI) and stroke volume index (SVI). For better quantification we will compare alterations in Microvascular Flow Index with cut off value of 2.6 AU directly with alterations in CI at minimal level of 2.2 L/kg/m2 where lower values in both parameters are highly correlating shock and are associated with mortality in the ICU.
With this project, we aim to validate Cytocam-IDF imaging as a routine monitoring tool in critically ill patients. To this end, we will compare Cytocam-IDF imaging to an invasive hemodynamic monitorization tool (PiCCO) in terms of comparability and linearity in critically ill patients.

Study objective

With this project, we aim to assess the correlation of PiCCO technology and Cytocam-IDF imaging as a routine monitoring tool in critically ill patients with circulatory compromise. To this end, we expect that there will be a comparability and linearity in critically ill patients which will result in quick and non-invasive monitoring of the circulation.

Study design

Daily

Intervention

Fluid and vasopressor use during resuscitation of critically ill patients.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
o Signed informed consent from the patient or his/her legal representative
o Be suitable for monitoring in the intensive care unit
o Should be older than 18 years
o Eligible for sublingual microcirculatory evaluation (not to have maxillofacial injury, bleeding in the mouth)
o Should be under PiCCO monitorization with routine clinic indication

Exclusion criteria

o <18 years old
o Woman of childbearing potential with a positive pregnancy test
o Refusal to participate in the study or demand to end study for any reason

o Resistance during the measurements of sublingual microcirculation will lead to end of the study.
o Moribund
o Intra-cardiac shunts, aortic aneurysm, aortic stenosis, mitral or tricuspid insufficiency,
o Pneumonectomy, macro lung embolism

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-03-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49817
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8445
CCMO	NL70350.098.19
OMON	NL-OMON49817

Study results