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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23604

Bron
NTR

Verkorte titel
ROUMI

Aandoening

Patients with any type of shock in the ICU

Ondersteuning

Primaire sponsor: Investigator initiated
Overige ondersteuning: Own ICU sources

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

o To investigate the correlation of microcirculatory parameter MFI measured with Cytocam-IDF with Cardiac Index measured using the trans-pulmonary hemodilution technique PiCCO

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Daily

Onderzoeksproduct en/of interventie

Fluid and vasopressor use during resuscitation of critically ill patients.

Contactpersonen

Publiek

HAGAziekenhuis
Sakir Akin

070-210 4307

Wetenschappelijk

HAGAziekenhuis
Sakir Akin

070-210 4307

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-03-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49817
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten