Detection of sepsis at the intensive care unit with non-invasive transcutaneous blood gas monitoring.

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The primary objective of this study is to determine the accuracy of the delta PCO2 (PaCO2-tcPCO2) and delta PO2 (tcPO2 -cPO2) levels for the detection of sepsis. The secondary aims are to determine the factors that influence delta PCO2 and delta PO2…

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON51879

Source
ToetsingOnline

Brief title
COSMOS

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Decreased and nonspecific blood pressure disorders and shock

Synonym
blood poisoning, sepsis

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,Sentec AG

Intervention

Keyword: intensive care, sepsis, transcutaneous blood gas monitoring

Outcome measures

Primary outcome

The main study endpoint is the accuracy determined with the AUC-ROC for the delta PCO2 (PaCO2 - tcPCO2) and delta PO2 (tcPO2 - cPO2) in patients with and without sepsis.

Secondary outcome

- To determine the factors influencing delta PCO2 and delta PO2.

- To determine and to determine a trend of delta PCO2 and delta PO2 levels over time during the onset and treatment of sepsis.

- The influence of ventilation and hemodynamics as measured by ventilation parameters, patient monitoring parameters and registration of applied vasopressors on skin perfusion by measuring delta PCO2, delta PO2, delta PI and delta heating power levels over time.

- Correlation of sensor value deviations and drift from blood gas sample values between measured tcPCO2, tcPO2, cPCO2, cPO2 and heating power to analyse the effects of skin temperature and vascularization on measurement accuracy.

- Correlation between delta PCO2, delta PO2 levels and delta heating power and pulse index (PI) from the pulse oximeter as indicator of impaired perfusion.

- Assessment of the measurement quality and accuracy in patients with microcirculatory impairment.

- Correlating the delta PCO2, delta PO2, delta PI and delta heating power to patient outcome.

- Determine the effect of the sensor location on the level and reliability of

the measurements.

- Determine the association between the delta PCO2 and blood flow measured

using laser Doppler spectroscopy.

Study description

Background summary

Sepsis has a high incidence worldwide and is still one of the major causes of death at the ICU. Early detection and treatment is crucial in the treatment of sepsis. Research has shown that the microcirculation could potentially be an indicator of sepsis, even in an early phase. During sepsis the microcirculation gets shunted from the arterioles to the venules, leaving the microcirculation hypercarbic and hypoxemic. These deviating carbon dioxide and oxygen levels during sepsis could potentially be measured with transcutaneous blood gas monitoring. Transcutaneous blood gas monitoring has been available since the 1970s and is used regularly in the premature neonatal population and adult sleep medicine. By locally heating the skin, carbon dioxide and oxygen diffuse to the skin surface reaching levels that correlate to arterial values. Past studies that applied a non-heated transcutaneous sensor during sepsis in adults have shown that non-heated transcutaneous blood gas measurements reflect the rise in tissue carbon dioxide levels. In addition, a recent study by our research group on transcutaneous blood gas monitoring in premature neonates confirmed impairment of the skin oxygen diffusion and consumption during sepsis or suspected sepsis. A study investigating the ability to detect sepsis in neonates using abovementioned methods is ongoing in neonates. The applicability in adults can be investigated using similar methods.
In this study, the condition of the microcirculation will be assessed by calculating the delta PCO2 between transcutaneous measurement of carbon dioxide (tcPCO2) and cutaneous carbon dioxide measurement of the skin (cPCO2) with an unheated sensor (sensor temperature set to 37-38 °C). Additionally, a similar assessment will be explored by calculating the PO2 difference, or delta PO2, between transcutaneous measurement of oxygen (tcPO2) and measurement of the partial arterial oxygen pressure PaO2 based on the oxygen saturation SpO2. Measurements will be performed with two OxiVenT sensors. The aim of this study is to evaluate the potential relation of delta PCO2 and delta PO2 to the microcirculation and thus sepsis.

Study objective

The primary objective of this study is to determine the accuracy of the delta PCO2 (PaCO2-tcPCO2) and delta PO2 (tcPO2 -cPO2) levels for the detection of sepsis. The secondary aims are to determine the factors that influence delta PCO2 and delta PO2 and to determine the trend of delta PCO2 and delta PO2 over time.

Study design

This study is a partially blinded prospective observational study. After informed consent is obtained, continuous transcutaneous measurement of the partial carbon dioxide and oxygen pressure, and continuous cutaneous measurement of partial pressures of carbon dioxide will be performed during a period of two weeks with two OxiVenT sensors. The sensors for cutaneous measurements will have a sensor temperature set to 37 to 38°C and will be blinded for the medical staff. The sensor temperature for transcutaneous measurements will be set to 41 to 42 °C, according to clinical protocol. Measurements will be used to evaluate the potential relation of these parameters to skin perfusion or microcirculation and sepsis. The values will be compared against blood flow measurements, measured with two laser Doppler spectroscopy sensors, as a clinical reference for the state of the microcirculation.

Study burden and risks

Transcutaneous carbon dioxide and oxygen sensors locally heats the skin to several degrees above the body temperature, potentially causing discoloration of the skin and eventually leading to burns when left in place for too long. As standard of care, protocols have been implemented to eliminate this risk by changing the measurement site every 8 hours. In practice, burns have not been seen in recent years and in particular not at all with this specific sensor. These standard protocols are adhered to in this study. The temperature of the unheated transcutaneous sensor will be set to 37- 38 °C so no additional risks or burden are added.

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

Sepsis group:
• Sepsis classified as 2 SIRS criteria and suspected infection
• Signs of hypoperfusion, requiring noradrenaline administration of at least 0.5 µg/min/kg
• Written informed consent.

Control group:
• No fulfillment of 2 SIRS criteria, nor suspected infection
• No signs of hypoperfusion, noradrenaline administration of less than or equal to 0.5 µg/min/kg
• Written informed consent.

Exclusion criteria

Sepsis group:
• No sepsis
• Skin condition contraindicating transcutaneous blood gas measurements.
• Absence of written informed consent.

Control group:
• Sepsis classified as 2 SIRS criteria and suspected infection
• Skin condition contraindicating transcutaneous blood gas measurements.

• Absence of written informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2022
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Transcutaneous blood gas sensor (Sentec OxiVenT Sensor)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2022
Application type:	First submission
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	NL76429.078.22