Detection of neonatal sepsis with non-invasive transcutaneous blood gas monitoring

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The primary objective of this study is to determine the relation of delta PO2 (PaO2-tcPO2) and delta PCO2 (tcPCO2-cPCO2) levels to sepsis. The secondary aims are to determine the factors that influence delta PO2 and delta PCO2 and to determine the...

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

Summary

ID

NL-OMON52386

Source
ToetsingOnline

Brief title
MOOSE

Condition

- Other condition
- Body temperature conditions
- Infections - pathogen unspecified

Synonym
blood poisoning, Sepsis

Health condition

prematuriteit

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,SenTec AG

Intervention

Keyword: Blood gas monitoring, Neonates, Sepsis, Transcutaneous measurements

Outcome measures

Primary outcome

The main study endpoint is the relation between delta PO2 (PaO2 - tcPO2) and

delta PCO2 (tcPCO2 - cPCO2) levels and sepsis.

Secondary outcome

Secondary study parameters include:

- Evaluation of the effect of patient age and time since birth on measurement

accuracy.

- The influence of ventilation and hemodynamic as measured by ventilation

parameters, patient monitoring parameters, and registration of applied

vasopressors

on skin perfusion by measuring delta PO2, delta PCO2, delta PI, and delta

heating power levels over time.

- Correlation of sensor value deviations and drift from blood gas sample values

between measured tcPO2, tcPCO2 levels, cPCO2, and heating power to analyze the

effects of skin temperature and vascularization on measurement accuracy.

- Correlation between delta PO2, delta PCO2 levels, and delta heating power and

Pulse Index (PI) from the pulse oximeter as an indicator of impaired perfusion.

- Correlation between delta PO2, delta PCO2 levels, delta PI, and delta heating power to HeRO-score during impaired microcirculation.

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

- Correlation of delta PO2, delta PCO2, and delta heating power levels to changes in NIRS oxygen levels.

- Correlating the delta PO2, delta PCO2, 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 relation between sepsis indicated by transcutaneous blood gas monitoring and questionnaires recording the clinical considerations for blood culturing by the attending neonatologist.

Study description

Background summary

Neonatal sepsis is one of the major causes of death in premature neonates. To date, there is no consensus on the definition of sepsis. Traditionally, sepsis is defined as a positive blood culture in which pathogenic bacteria are shown, combined with clinical decline. 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 hypoxemic and hypercarbic. These deviating oxygen and carbon dioxide 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. By locally heating the skin, carbon dioxide and oxygen diffuse to the skin surface that correspond to arterial values. A recent study by our research group on transcutaneous blood gas monitoring in premature neonates confirms impairment of the skin oxygen diffusion and consumption during sepsis

or suspected sepsis, while carbon dioxide diffusion remains uninfluenced. In this study, the condition of the microcirculation will be assessed by calculating the PO2 difference, or delta PO2, between transcutaneous measurement of oxygen (tcPO2) and measurement of the arterial oxygen saturation PaO2 based on the SpO2. In addition and 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 °C) will be assessed. Measurements will be performed with two transcutaneous blood gas sensors and a standard of care pulse oximeter. The aim of this study is to evaluate the potential relation of delta PO2 and delta PCO2 to the microcirculation and thus sepsis.

Study objective

The primary objective of this study is to determine the relation of delta PO2 (PaO2-tcPO2) and delta PCO2 (tcPCO2-cPCO2) levels to sepsis. The secondary aims are to determine the factors that influence delta PO2 and delta PCO2 and to determine the trend of delta PO2 and delta PCO2 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 transcutaneous blood gas sensors. The sensors for cutaneous measurements will have a sensor temperature set to 37 °C and will be blinded for the medical staff. The sensor temperature for transcutaneous measurements will be set to 42-43 °C, according to clinical protocol. Measurements will be used to evaluate the potential relation of these parameters to skin perfusion or microcirculation and sepsis.

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 in our neonatal and paediatric intensive care departments to eliminate this risk by regularly changing the measuring site to prevent burns. 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 blood gas sensor will be set to 37 °C (or core body temperature of the neonate) so no additional risks or burden are added.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

A gestational age of 24 weeks up to and including 31 weeks at the time of inclusion.
A pulse oximeter.
Written informed consent

Exclusion criteria

A gestational age of 32 weeks or more at the time of inclusion.
Skin condition contraindicating transcutaneous 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)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2021
Enrollment:	64
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	19-10-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-11-2022
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	NL74106.078.20