Clinical evaluation of a new tcPCO2 sensor in neonates: A pilot study.

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

Summary

ID

NL-OMON46003

Source
ToetsingOnline

Brief title
NEO-OTC100

Condition

- Other condition
- Body temperature conditions
- Neonatal respiratory disorders

Synonym
premature birth, Prematurity

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 AG

Intervention

Keyword: Blood Gas Monitoring, Carbon dioxide, Neonates, Transcutaneous measurement

Outcome measures

Primary outcome

The main study endpoint is the agreement between carbon dioxide values measured with the new sensor and standard of care blood gas sampling. In addition the measurement drift is determined.

Secondary outcome

- To evaluate sensor accuracy during hypercapnia and hypocapnia.

- To correlate the transcutaneously measured carbon dioxide levels to the oxygen levels measured with standard of care cerebral near-infrared spectroscopy (NIRS) to determine the vascular influence of CO2 levels on cerebral oxygenation.

- To evaluate the influence of the measured ventilation parameters, patient monitoring parameters and hemodynamics including the applied vasopressors on sensor accuracy and functioning

- To evaluate the effects of local skin heating by the new sensor as an indicator of application safety using the standard application protocols in our hospital.

- To correlate sensor value deviations and drift from blood gas sample values between measured tcPCO2 levels to analyze the effects of skin temperature and

vascularization on measurement accuracy.

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

accuracy.

- To assess the measurement quality and accuracy in patients with

microcirculatory impairment.

Study description

Background summary

A large portion of the neonates in the neonatal intensive care unit (NICU) requires respiratory support. For measuring the effects of respiratory support and adjustment of ventilator settings it is of vital importance to measure carbon dioxide and oxygen within the body. Commonly the arterial carbon dioxide pressure is measured through arterial or capillary blood sampling. Neonates have a small circulating blood volume, limiting the amount of blood that can be withdrawn. In addition blood sampling is done with large intervals, and capillary blood sampling causes discomfort. An alternative is the transcutaneous blood gas measurement of carbon dioxide. By locally heating the skin carbon dioxide evaporates from the surface, in optimal conditions up to arterial levels. The current sensors are based on an electrochemical measurement technique, which suffers from measurement 'drift', requiring frequent calibration. As a consequence transcutaneously measured carbon dioxide levels often inadequately represent arterial levels. SenTec AG has recently developed a new transcutaneous sensor for measuring carbon dioxide, which was developed with the aim to be free of measurement drift. This is a pilot study in which the sensor is used for the first time in humans for the assessment of technical feasibility in the most relevant patient population and most challenging conditions. The main aim of the study is to evaluate accuracy to standard of care blood sampling and to determine measurement drift.

Study objective

The primary objective of this pilot study is to determine the technical feasibility of the sensor in clinical practice. Accuracy is investigated with an agreement analysis of transcutaneous measurements and standard of care blood sampling, measurement drift is quantified over time.

Study design

This study is a prospective, blinded observational pilot study. After informed consent is obtained we will perform continuous transcutaneous measurements of partial carbon dioxide pressure for 72 hours with the new sensor. The obtained values are compared to arterial carbon dioxide partial pressure measurements from standard of care blood gas withdrawals.

Study burden and risks

During 72 hours we will perform non-invasive measurements, of which the burden is minimal. The sensor is attached with a skin-friendly adhesive which is regularly used in the NICU. Furthermore, in this study sensor temperature is set to 41 °C, which is lower than the temperature of currently used transcutaneous sensors at the NICU (42-43 °C). For sensor site changes we will adhere to the existing hospital protocol. No additional blood will be drawn, only results from standard of care blood sampling will be used.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

A gestational age of 24 weeks or older at the time of inclusion.
An arterial catheter.
Written informed consent.

Exclusion criteria

Absence of written informed consent.
Skin condition contraindicating transcutaneous measurements.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	tcPCO2 sensor
Registration:	No

Ethics review

Approved WMO Date:	09-07-2018
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	NL66033.078.18