Official Title: Calibration and Validation of Masimo's O3 Regional Oximetry Device in Neonates, Infants and Children Undergoing Cardiac Catherization

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Calibration and Validation of Masimo's O3 Regional Oximetry Device in Neonates, Infants and Children Undergoing Cardiac Catheterization

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Abstract:

This study will prospectively collect regional oximetry data from pediatric and neonatal subjects, using a new regional oximetry device (O3™, Masimo, Irvine, CA). The O3 system, consists of a bedside monitor, the POD (cerebral oximetry unit) and near infra-red spectroscopy (NIRS) sensors. To calibrate and validate the technology for cerebral oxygen saturation in this patient population, reference blood samples will be collected from the pediatric subjects who are presenting for diagnostic or therapeutic cardiac catheterization at Stanford University Medical Center.

Purpose:

The aim of the present study is to collect data for calibration and validation of a newly designed O3 cerebral oximeter in pediatric and neonatal patients. Data from cutaneously placed forehead sensors will be continuously collected along with peripheral pulse oximetry. Since cerebral oxygen saturation is a combination of arterial and venous saturations reference blood samples will be collected simultaneously from the artery and the jugular venous bulb.

Background:

Masimo Corporation is the developer of noninvasive technologies for the measurement and monitoring of physiological variables, such as arterial oxygen saturation (SpO_2), total hemoglobin concentration (SpHb), carboxyhemoglobin concentration (SpCO), methemoglobin concentration (SpMet) and acoustic respiration rate monitoring (RRa). These technologies are noninvasive, and have a good patient safety record. This study describes a data collection procedure for the development and calibration of a new regional oximetry system(Masimo O3™) that has originally been developed for adult populations, has received CE mark for use in

the European Union (EU) and is currently pending FDA 510k clearance in the United States for use in adult patients. O3 regional oximetry has recently been evaluated in adult volunteer subjects and found to perform with equivalent or better absolute accuracy and trending accuracy as other commercially available regional oximetry systems.

The O3 regional oximetry sensors contain a 4-wavelength LED emitter, and two light detectors for the detection of deep tissue and superficial oxygenation. The system is designed to allow the near-infrared light to superficially penetrate the scalp, skull and brain tissue. Using multiple wavelengths of light and spatially distributed photo-detectors to interrogate the deep tissue, the O3 system measures regional saturation of oxygen (rSO_2) by establishing a relationship between the light absorbed by the tissue and its oxygen saturation.

The accuracy validation study for the O3 system in an adult population reported a mean bias of 0.4%, absolute root-mean-squared accuracy of 4.0% and trending root-mean-squared accuracy of 2.1%. These accuracy statistics are significantly better than the test accuracy of the most commonly used regional oximeter (INVOS) and match the accuracy of the laser-based Foresight system. The O3 system is much more compact system, technology packed in a small POD, [redacted]

Finally, the Masimo O3 POD connects to the standard bedside monitor (recently released as Masimo Root that allows simultaneous connection and monitoring of other clinical parameters, including all RainbowSET parameters, SEDLine, Respiration rate, etc., and is configured to connect to 3rd party devices as well).

During data collection, in additional to arterial and venous blood oxygen saturation, other relevant hemodynamic information needs to be recorded. A shift in cerebral vascular tone may change the ratio of arterial to venous blood in the light path.

Because changes in arterial carbon dioxide content are known to change cerebral vascular tone, pH and PCO_2 will be measured and recorded on each blood sample analysis.

LOCATION

The pediatric cardiac catheterization laboratory at Stanford University Medical Center

EQUIPMENT AND MATERIALS

Hospital Standard of Care equipment will be used for the catheterization procedure. In addition the following study specific equipment will be used and supplied by Masimo Corp.

- Masimo O3™ regional oximetry device with forehead sensors and O3™ modules
- Masimo Root Pulse CO-Oximeter and disposable Masimo SET optical sensors

Laboratory co-oximeter and blood gas analyzer for determination of arterial (SaO_2) and venous (SvO_2-) and blood gases for pH, pCo2 and PO2

PROCEDURE

- This is a prospective, clinical observational study in pediatric patients with heart disease to collect cerebral recordings of an investigational device sensor (Masimo O3™ regional oximetry system) placed on the subject's forehead as well as oxygen saturation values from arterial blood samples and jugular bulb blood samples for the development and evaluation of algorithms Parental or legal guardian consent and where possible subject assent will be obtained to act as a Human Research Subject prior to being enrolled in the study.
- Demographic information and medical history will be obtained for each enrolled subject prior to the start of the procedure.

An optical finger pulse oximeter sensor to measure SpO2, PI and PR will be placed for continuous monitoring throughout the procedure.

- One or two (depending on size of forehead) Masimo O3™ cerebral oximetry sensors will be placed on the subjects forehead, then connected to a Masimo Root bedside monitor through a Masimo O3™ module.
- A laptop with [redacted] software [redacted] will be connected to the Root bedside monitor for continuous data collection of all O3 and Masimo SET parameters (SpO2, PR, PI).
- A cardiac catheterization procedure will be performed following institutions standard of care.
- The cardiac interventionist will begin the catheterization process as per standard of care and obtain arterial and venous access. The venous catheter tip will be directed towards the jugular bulb and its correct localization confirmed by fluoroscopy. [redacted] samples will be placed in ice and analyzed as soon as possible. The rest of the catheterization procedure will be as per standard of care. [redacted]
- [redacted]
- At the conclusion of the study devices and data recording will be stopped, and study sensors will be removed.
- Subjects will be followed 48 hrs. after the procedure with a phone call to assess any study related adverse event

Subjects

Enrollment will not exceed 50 subjects. This sample size is expected to be sufficient for algorithm development and validation.

Inclusion criteria

- Pediatric patients undergoing cardiac cathetheterization procedure for treatment or diagnosis of cardiovascular disease
- 1 day to less than 18 yrs. of age
- Weight between 3.5 and 40 kg
- parental or legal guardian consent and subject assent

Exclusion criteria

- Failure to obtain written consent
- Equal or more than 18 years in age
- Weigh more than 40 kg or less than 3.5 kg
- Jaundice with bilirubin levels higher than the reference range
- Subject has skin abnormalities affecting the digits such as psoriasis, eczema, angioma, scar tissue, burn, fungal infection, substantial skin breakdown, nail polish or acrylic nails that would prevent monitoring of SpO_2 levels during the study or placement of cerebral oximeter

Measures taken to protect the rights and welfare of subjects

All subjects will be monitored closely throughout the study.

The following measures will be taken to insure the privacy of the subjects:

- A code (identification) number for each subject will be kept on file.
- Only their corresponding identification number will identify subjects.
    - Access to the documents and data will only be made to the investigators in the study.
    - The confidentiality of these documents will be protected to the extent provided by the law.
- **Risks, Benefits and Compensation:**

- Risks: Noninvasive measurement with cerebral and pulse oximetry: The risk from noninvasive oximetry devices is minimal. The technology uses non-invasive optical sensors.
- Sensor risks: As with all optical sensors, the investigational device has the risk of thermal burn. The design includes safeguards, and this risk is believed to be low. Pressure damage may occur to the tissue if the sensor is placed too tightly. Sensors will be attached with adhesive, and may be secured by a supplemental headband. This risk is believed to be low. Optical exposure is minimized by procedure and low power.
- Benefits: There will be no direct benefits to the enrolled patients. Future benefits to patients might include a reduction in invasive procedures due to the ability to trend moment-by-moment physiological parameters such as regional oximetry.
- Compensation: Study participants will not receive compensation for participation in the study.

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