

# Normal values of non-invasive measurements of cerebral and muscle tissue oxygenation using near infrared spectroscopy in healthy near term and term newborn infants.

Published: 22-11-2017

Last updated: 12-04-2024

To obtain reference values of rsO<sub>2</sub> of cerebral and muscle tissue measured by NIRO 200 NX for (relatively) healthy near term and term neonates.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON44253

### Source

ToetsingOnline

### Brief title

Cerebral and muscle tissue oxygenation

### Condition

- Neonatal and perinatal conditions

### Synonym

hypoxic-ischemic encephalopathy

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Brain, Muscle, Near infrared, Oxygenation

## Outcome measures

### Primary outcome

Normal reference values of rsO<sub>2</sub> of cerebral and muscle tissue in the first day of life.

### Secondary outcome

None.

## Study description

### Background summary

Monitoring of tissue oxygenation is considered as an essential component in the monitoring and treatment of severely ill and hemodynamically unstable neonates on a neonatal intensive care unit (NICU) and of neonates during anesthesia in a surgical procedure.

Spatially resolved near infrared spectroscopy (NIRS) is a method for non-invasive and continuous measurement of regional oxygen saturation (rsO<sub>2</sub>) in tissue. Using this non invasive technique, the ratio of oxyhemoglobin and deoxyhemoglobin in the tissue can be measured and expressed in rsO<sub>2</sub> in percent. Changing the rsO<sub>2</sub> reflects a change in oxygen supply and oxygen demand in tissue, indicating decrease of rsO<sub>2</sub> tissue hypoxia. With this method it is possible to measure the rsO<sub>2</sub> in cerebral and muscle tissue.

Measurement of the cerebral rsO<sub>2</sub> has been found to be useful in various clinical conditions, especially during cardiac surgery as an indicator of cerebral oxygenation and perfusion. There is a good relationship between venous oxygen saturation in the jugular vein and rsO<sub>2</sub>. To date, no valid validation studies have been published yet. The normal reference values \*\*of rsO<sub>2</sub> for term and near term newborn in the literature are diverge and appear to be dependent on the brand of the NIRS device. In previous CMO applications, we have determined normal rsO<sub>2</sub> values \*\*in cerebral and muscle tissue in healthy near

term and term neonates with NIRS equipment of INVOS.

In the meanwhile, together with the Department of Anesthesiology, we have purchased NIRS NIRO 200 NX (Hamamatsu) equipment for monitoring of cerebral oxygenation in neonates during anesthesia in a surgical procedure. The values \*\* of rsO<sub>2</sub> of NIRO 200 NX appear to differ from the values \*\* of INVOS. The normal reference values \*\* of rsO<sub>2</sub> for cerebral and muscle tissue are not known from literature. It is therefore important to determine normal reference values \*\* for cerebral and muscular rsO<sub>2</sub> in healthy near term and term neonates and also to investigate the relationship between these variables. With the knowledge of normal reference values, pathological conditions can be quickly recognized and targeted therapies can be set to restore normal conditions.

## **Study objective**

To obtain reference values of rsO<sub>2</sub> of cerebral and muscle tissue measured by NIRO 200 NX for (relatively) healthy near term and term neonates.

## **Study design**

On the first day after birth, a continuous measurement of the regional oxygen saturation (rsO<sub>2</sub>) in the brain and in the quadriceps muscle will be performed using NIRS (NIRO 200 NX) for 30 minutes. This is a non-invasive method, using a local sensor that emits light locally, the change in regional oxygen saturation can be measured directly in the mixed vascular bed directly below the sensor. The sensors are attached to the skull and the upper leg with a double-sided adhesive ring and with an elastic bandage.

The following physiological variables will also be recorded simultaneously, continuously and non-invasively: heart rate and arterial O<sub>2</sub> saturation (saO<sub>2</sub>, puls oximetry)

## **Study burden and risks**

NIRS is non-invasive and harmless to tissue. The burdening and risk for the patient are almost nil

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

- Newborns admitted in maternity ward or neonatal medium care
- Uncomplicated pregnancy
- Gestational age 34-37 weeks (near term) or 37-42 weeks (term)
- Parental consent

### Exclusion criteria

- Congenital heart defect
- Perinatal asphyxia
- Small for gestational age (birth weight < P2.3)
- Large for gestational age (birth weight > P97.7)
- Evident clinical or laboratory confirmed sepsis

## Study design

### Design

**Study type:** Observational non invasive

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2018
Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	22-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL62083.091.17