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 rsO2 of cerebral and muscle tissue measured by NIRO 200 NX for (relatively) healthy near term and term neonates.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	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 rsO2 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 (rsO2) in tissue. Using this non invasive technique, the ratio of oxyhemoglobin and deoxyhemoglobin in the tissue can be measured and expressed in rsO2 in percent. Changing the rsO2 reflects a change in oxygen supply and oxygen demand in tissue, indicating decrease of rsO2 tissue hypoxia. With this method it is possible to measure the rsO2 in cerebral and muscle tissue.
Measurement of the cerebral rsO2 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 rsO2. To date, no valid validation studies have been published yet. The normal reference values **of rsO2 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 rsO2 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 rsO2 of NIRO 200 NX appear to differ from the values **of INVOS. The normal reference values **of rsO2 for cerebral and muscle tissue are not known from literature. It is therefore important to determine normal reference values ** for cerebral and muscular rsO2 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 rsO2 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 (rsO2) 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 O2 saturation (saO2, 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
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL
Scientific

Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL

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 laborartory 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