An observational study on the microcirculation in healthy children

Published: 16-01-2018
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To establish a healthy control group for microcirculatory parameters for current and future studies on the paediatric microcirculation.

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

Summary

ID

NL-OMON44428

Source
ToetsingOnline

Brief title
HuMBLE

Condition

- Heart failures

Synonym
not applicable

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,Sophia Stichting Wetenschappelijk Onderzoek Grant project no. S17-06

Intervention

Keyword: children, hemodynamic monitoring, microcirculation

Outcome measures

Primary outcome

With incident dark field illumination (IDF) imaging, a video-microscopy technique that allows the direct visualization of the sublingual microcirculation, variables of vessel density (total vessel density (TVD) and perfused vessel density (PVD)), two indexes of vascular perfusion (microvascular flow index (MFI) and proportion of perfused vessels (PPV)) and a heterogeneity index of the flow (heterogeneity index (HI)) will be collected.

Demographic data and medical history will also be assessed before measurements.

Secondary outcome

Not applicable.

Study description

Background summary

The classic approach to evaluate circulatory failure is focused on the macrocirculation (e.g. blood pressure and cardiac output). However, accurate measurements of these parameters require techniques, which are invasive and unreliable and therefore not preferable in children. Bedside monitoring of the microcirculation with handheld video-microscopy cameras offers new ways for a non-invasive approach for hemodynamic monitoring in critically ill children. The microcirculation consists of all vessels smaller than 100 micrometres (mostly arterioles, capillaries and venules) and is responsible for the actual oxygen and nutrient exchange of cells and tissues. Implementing microcirculatory targets could therefor aid in assuring optimal oxygen delivery, as we have shown under a variety of conditions in new-borns and children admitted to the intensive care. Despite its vital role, minimal research has been done on the microcirculation in healthy children and research in adults cannot be extrapolated. In order to study the pathophysiology of the

microcirculation, first, normal ranges of microcirculatory parameters in healthy children have to be established.

Study objective

To establish a healthy control group for microcirculatory parameters for current and future studies on the paediatric microcirculation.

Study design

A prospective observational cohort study in primary, secondary and high schools in Rotterdam and at our level III children*s university hospital.

Study burden and risks

No risks are associated with participation and the burden of the study is minimal. The used video microscopy technique offers the opportunity to visualize and analyse the microcirculation in a non-invasive manner, proven by studies in children of different age groups conducted in our institution in the past. The device is gently positioned towards the sublingual mucosa and 5 video clips of each 6 seconds are recorded. The procedure is short of duration, safe and pain free, and the live videos can be seen by the children themselves. Children until 7 years old will be measured after induction for their elective surgery. Due to their young age measurements can only be performed in a sedated state. Anaesthesia will be protocolized following current clinical practice. Children from the age of 6 and up will be measured awake. The children and/or parents will be asked to fill in a one-page questionnaire on the basic information and medical history of the child. In order to study the pathophysiology of the microcirculation, first, normal ranges of microcirculatory variables in healthy children have to be established. This data is currently not available and data from healthy adults is scarce and cannot be extrapolated to children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
For group (A):
- Healthy children from the age of 0 until 7 years old;
- Undergoing non-cardiac elective surgery;
- Mechanical ventilation through an endotracheal tube;
- Parental informed consent. ;For group (B):
- Healthy children from the age of 6 until 18 years old;
- Informed consent:
o Parental informed consent for all children from the age of 6 until 16 years old;
o Informed co-consent of children from the age of 12 until 16 years old;
o Informed consent of children from the age of 16 until 18 years old.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
For group (A):
- Absence of parental informed consent;
- Preterm new born (adjusted age * 36 weeks);
- Cardiovascular, renal or oncological disease;
- Mechanical or spontaneous ventilation through a larynx mask airway.;For group (B):

- Absence of (parental) informed consent;
- Cardiovascular, renal or oncological disease;
- Use of drugs;
- Smoking;
- Pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-03-2018
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	14-05-2018
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	NL62060.078.17