The effect of changing CO2 levels on perioperative cerebral and microcirculatory hemodynamics in infants undergoing laparoscopic surgery

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Primarily, to assess the effect of changing CO2 levels on the sublingual microcirculation, cerebral oxygenation, and cerebral perfusion. Secondarily, to assess if and how sublingual microcirculatory parameters, parameters of cerebral oxygenation,...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON48061

Source ToetsingOnline

Brief title The XXX monitoring Study

Condition

• Gastrointestinal tract disorders congenital

Synonym

Diseases that require surgical correction through laparoscopic surgery

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

Intervention

Keyword: Cerebral hemodynamics, Laproscopic surgery, Microcirculation, Noninvasive hemodynamic monitoring

Outcome measures

Primary outcome

- End tidal CO2 (etCO2, kPa);
- Transcutaneous partial pressure CO2 (PCCO2, kPa);
- Sublingual microcirculation: parameters of vessel density (total vessel

density (TVD, mm/mm2) and perfused vessel density (PVD, mm/mm2)) and parameters

of vascular perfusion (microvascular flow index (MFI), proportion of perfused

vessels (PPV, %), red blood cell velocities (RBCV, mm/s) and heterogeneity

index of flow (heterogeneity index (HI)));

- Cerebral oxygenation: regional cerebral oxygen saturation (rScO2, %);
- Cerebral perfusion: cerebral blood flow velocities (CBFV, cm/s) of the

lateral striate artery and the medial cerebral artery;

- Cerebral activity: neuronal electrical activity and background patterns over

time.

Secondary outcome

Not applicable

Study description

Background summary

Carbon dioxide (CO2) is the primary insufflation gas used for pneumoperitoneum

during laparoscopy and yields systemic and regional hemodynamic alterations. The effects of these alterations on local and cerebral tissue oxygenation have not yet been fully understood, especially in infants.

Study objective

Primarily, to assess the effect of changing CO2 levels on the sublingual microcirculation, cerebral oxygenation, and cerebral perfusion. Secondarily, to assess if and how sublingual microcirculatory parameters, parameters of cerebral oxygenation, and parameters of cerebral perfusion are correlated.

Study design

A single center observational prospective study.

Study burden and risks

No risks are associated with participation and the extend of the burden is limited. Handheld vital microscope (HVM), Near Infrared Spectroscopy (NIRS), Doppler Cranial Ultrasonography (Doppler CUS), and Amplitude Integrated Electroencephalogram (aEEG) offer the opportunity to assess the sublingual microcirculation, cerebral oxygenation, cerebral blood flow and cerebral activity in a non-invasive manner, proven by studies in children of different age groups conducted in our institution in the past and by the integration of NIRS and aEEG in standard clinical care. The HVM is gently positioned on the sublingual mucosa and 5 video clips of each 6 seconds are recorded. Due to their young age measurements can only be performed in a sedated state. NIRS is applied through transcutaneous sensors placed on the forehead, without being harmful to the tissue or causing discomfort to the patient. The Doppler CUS probe is gently positioned on the anterior fontanelle to allow direct visualization of intracranial vessels. The aEEG is applied with the aid of adhesive sensors placed on the head, which have no reported side effects. All procedures are safe and pain-free and will not interfere with surgical and anesthetic procedures. This study will help us better understand the effects of CO2 pneumoperitoneum on local and cerebral tissue oxygenation in infants, especially as their brain is still developing.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

Cardiovascular healthy children 0 to 1 year of age undergoing laparoscopic surgery

Exclusion criteria

- Absence or refusal of parental informed consent;
- Preterm new born (adjusted age * 36 weeks);
- Cardiovascular, pulmonary, renal, oncological disease;
- Genetic syndrome

Study design

Design

Study type:Observational non invasiveMasking:Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	16-08-2019
Enrollment:	15
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	28-08-2019
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 CCMO **ID** NL70270.078.19