HFR Doppler CUS during inguinal hernia repair
Changes in cerebral perfusion measured by high frequency Doppler cerebral ultrasonography during anesthesia for inguinal hernia repair

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19965

Source
NTR

Brief title
HFR Doppler CUS during inguinal hernia repair.

Health condition

Inguinal Hernia repair

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

To assess the effect of standard anesthetic procedures on cerebral blood flow measured with CBFV and HFR Doppler CUS during inguinal hernia repair.

Secondary outcome

To correlate CBFV and HFR Doppler CUS to routine monitoring techniques including heart rate, blood pressure, peripheral oxygen saturation, and regional cerebral oxygenation.

Study description

Background summary

Rationale: Toddlers undergoing major surgical procedures are at risk of perioperative brain lesions. Present monitoring techniques provide insufficient information about brain perfusion. In a feasibility study we showed that non-invasive conventional and high framerate resolution Doppler cerebral ultrasonography (HFR Doppler CUS) may provide information about brain perfusion.
Objective: To assess the difference between induction of anesthesia, standard fluid load and emergence of anesthesia on cerebral blood flow measured with cerebral blood flow velocity (CBFV) and HFR Doppler CUS.
Study design: Single-center prospective observational cohort study
Study population: Children 0 to 1 year of age (born premature and a term) without major cardiovascular or pulmonary disease undergoing surgical correction of unilateral or bilateral inguinal hernia will be eligible for inclusion.
Intervention: Patients will be treated according to standard medical treatment.
Main study parameters/endpoints: The main study parameter will be the change in cerebral brain perfusion using conventional Doppler and HFR Ultrasound cerebral blood flow velocities (CBFV, cm/s) of the lateral striate artery and the medial cerebral artery over 5 phases of anesthesia for inguinal hernia repair.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
No risks are associated with participation and the extend of the burden is limited. Doppler CUS offers the opportunity to assess the cerebral blood flow in a non-invasive manner. Doppler CUS examination is standard clinical care at the neonatal intensive care unit to detect anatomical abnormalities. The Doppler CUS probe is positioned on the anterior fontanelle to allow direct visualization of intracranial vessels. The results from this study will show if conventional and HFR Doppler will be able to detect changes in cerebral perfusion in the perioperative period which cannot be detected with conventional monitoring techniques.

Study objective

We hypothesize that CBFV measurement in the ICA and pACA using Doppler CUS will become a monitoring technique to guide optimizing cerebral perfusion in the perioperative phase. Furthermore, HFR Doppler CUS will provide additional quantitative information of cerebral perfusion of the cerebral cortex.

Study design

1. At the operating room before induction of anesthesia
2. After induction of anesthesia
3. After administration of caudal anesthesia
4. During surgery, after administration of standard fluid bolus (10ml/kg), before emergence of anesthesia
5. After emergence of anesthesia in the anesthesia recovery room when the patient is awake

Intervention

Observational study

Contacts

Public
Erasmus MC
Jurgen de Graaff

+31614184374
Scientific
Erasmus MC
Jurgen de Graaff

+31614184374

Eligibility criteria

Inclusion criteria

Children 0 to 1 year of age (born premature and a term) without major cardiovascular or pulmonary disease undergoing surgical correction of unilateral or bilateral inguinal hernia

Exclusion criteria

• Absence or refusal of parental informed consent
• Extreme preterm born (< 28 weeks)
• Emergency surgery for incarcerated inguinal hernia
• Major cardiovascular, pulmonary, renal, oncological disease
• Genetic syndrome

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion

Date:	18-01-2021
Application type:	First submission

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
NTR-new	NL9749
Other	METC ErasmusMC : MEC-2021-0187

Study results