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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19965

Bron
NTR

Verkorte titel
HFR Doppler CUS during inguinal hernia repair.

Aandoening

Inguinal Hernia repair

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Observational study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
NA

Ethische beoordeling

Positief advies

Datum:	18-01-2021

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9749
Ander register	METC ErasmusMC : MEC-2021-0187

Resultaten