Neuromonitoring during surgical repair of congenital diaphragmatic hernia and esophageal atresia patients

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The overall aim of this observational prospective study is to evaluate the association between a) the trajectory of cerebral oxygenation, activity and perfusion as evaluated by NIRS, aEEG, Zonare Doppler Ultrasound and Cytocam-IDF during and 24…

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

Summary

ID

NL-OMON49066

Source
ToetsingOnline

Brief title
The NeMo CDH/EA study

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal therapeutic procedures

Synonym
Birth defect of the diaphragm. hole in the diaphragm, esophageal birth defect

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: congenital diaphragmatic hernia, esophageal atresia, neuromonitoring, surgery

Outcome measures

Primary outcome

The overall aim is to evaluate the association between cerebral oxygenation, activity and perfusion as evaluated perioperative by NIRS, aEEG, Zonare Doppler Ultrasound and Cytocam-IDF and evaluation of growth and neurodevelopment within the first two years of age.

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Secondary outcome

* Evaluation by NIRS, aEEG, Zonare Doppler ultrasound and Cytocam-IDF to compare open, minimal access surgery (MAS) and conversion from MAS to open surgery of the diaphragm defect for 24 hours.

* Transcutaneous CO2 measurements

* Mitochondrial saturation

* Pre- and postoperative intensive care management:

* Ventilation settings and need of oxygen

* Use of vaso-active medication

* (Postoperative) pain scores every eight hours (COMFORT scores)

* Number of ventilator free days at day 28

* Length of stay (LOS)

* Prenatal screening ultrasound results for CDH neonates

* Cranial ultrasound pre- and postoperative, at discharge from paediatric centre

* Arterial blood gas analysis perioperative

* Contralateral renal and quadriceps muscle tissue oxygenation starting 3 hours

before surgery till 24 hours postoperative

* Recurrence rate in the two years after surgery

* Neurodevelopmental outcome at 6, 12, 18 and 30 months of age

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Study description

Background summary

Neonatal circulatory homeostasis is influenced by multiple factors in the perioperative period and general anesthesia affect the hemodynamics negatively during surgical repair. Traditional surgical management of CDH consists of repair by laparotomy and for EA by thoracotomy. In the last decade, minimal access surgery (MAS) became more popular because literature reports less surgical stress, faster recovery and shorter hospitalization after MAS. Therefore, thoracoscopic repair of CDH and EA is still being further explored.
A number of centres perform thoracoscopic repair when patients are cardiopulmonary stable. Cardiopulmonary stability criteria still differ between centres and have been published in nine retrospective studies. Patients who do not fulfil the criteria will undergo open repair. Neonates are prone for intraoperative acidosis regarding type of surgery, due to the intrathoracic manipulation by the surgeon a ventilation-perfusion mismatch may arise. During minimal invasive thoracoscopic surgery with CO2 insufflation and a pneumothorax, the acidosis is more severe. The anesthesiologist aims to compensate this acidosis by adapting the ventilation with increased tidal ventilation. This results in a higher mean ventilation pressure which is associated with a compromised venous return with decreased right ventricle preload. The aim of optimized CO is to maintain adequate tissue perfusion and oxygenation.
The artificial pneumothorax, mechanical pressure and acidosis may affect tissue perfusion in general. Quantitative analysis of this effect has always been difficult. Bishay et al. showed substantial arterial blood gas changes during thoracoscopic repair in CDH and EA, but this finding was based on only ten patients. Our pilot study showed severe respiratory acidosis with changes in tissue perfusion. This is seen on macro- (Doppler ultrasound), micro-

(microcirculation) and cellular (mitochondrial saturation) level.
Therefore, in patients with CDH and EA (particularly those with a good prognostic outcome) it is not clear whether the balance between pros and cons of MAS is in favour or against its use. One particular aspect relates to the long-term outcomes of MAS in CDH and EA. Neurodevelopmental outcome, especially in the long term, is still under documented. We do know however, that neurodevelopment rests on complex interactions between preoperative, perioperative and postoperative events. This might be related to factors such as the surgical procedure itself, effects of anaesthetic medication and perioperative hypoxic/ischemic brain injury. Neurodevelopmental outcome may be influenced by the use of different surgical and anaesthesiological techniques.

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Study objective

The overall aim of this observational prospective study is to evaluate the association between a) the trajectory of cerebral oxygenation, activity and perfusion as evaluated by NIRS, aEEG, Zonare Doppler Ultrasound and Cytocam-IDF during and 24 hours after surgery and b) long-term psychomotor outcome as evaluated by CHIL-follow up at age 2. In addition, evaluation of changes in cerebral oxygenation, activity and perfusion as evaluated by NIRS, aEEG, Zonare Doppler Ultrasound and Cytocam-IDF and a comparison between open and minimal access surgery of the diaphragm/esophageal defect. The analysis will help to determine whether neuromonitoring outcomes should be used to determine whether, and for which patients, minimal access surgery is safe.

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Study design

Multi-centre observational prospective study.

Study burden and risks

Subjects will have no direct benefits of participating in this study. The neuromonitoring is non-invasive. The surgical technique is regularly performed in our departments. The burden for the patient is expected to be very low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Newborns

Inclusion criteria

Surgical repair should be performed after clinical stabilization, defined as follows:
* Mean arterial blood pressure normal for gestation.
* Preductal saturation levels of 85-95% on FiO2 below 50%
* Lactate below 3 mmol/l
* Urine output more than 1 ml/kg/h
Repair can be performed while the patient is on ECMO

Exclusion criteria

Associated major cardiac anomalies/chromosomal anomalies or syndromes with major cognitive impairment excluding surgical repair of the diaphragmatic/esophageal defect due to futility.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2017
Enrollment:	45
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	31-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	03-09-2019
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

ID: 23869
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59526.078.17
Other	NTR TC=7160