NEUROMONITORING DURING SURGICAL REPAIR OF CONGENITAL DIAPHRAGMATIC HERNIA AND ESOPHAGEAL ATRESIA PATIENTS

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Association between cerebral oxygenation and activity as evaluated perioperative by NIRS and aEEG and evaluation of growth and neurodevelopment within the first two years of age.

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

Samenvatting

ID

NL-OMON23869

Bron
Nationaal Trial Register

Verkorte titel
NEMO CDH/EA STUDY

Aandoening

Surgical repair of Congenital Diaphragmatic Hernia or Esophageal Atresia

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The overall aim is to evaluate the association between cerebral oxygenation and activity as evaluated perioperative by NIRS and aEEG and evaluation of growth and neurodevelopment within the first two years of age.

Toelichting onderzoek

Achtergrond van het onderzoek

RATIONALE: Traditional open surgical management of congenital diaphragmatic hernia (CDH) and esophageal atresia (EA) consists of either laparotomy or thoracotomy. Minimal access surgery has gained popularity in the last decade because of its potential benefits. The outcome of
thoracoscopic surgery is still in discussion and the long-term effects on neurodevelopment are
unknown. Patch repair is feasible thoracoscopically, but more difficult and time consuming.

OBJECTIVES: To evaluate the significance of non-invasive neuromonitoring (NIRS and aEEG) during surgical repair and the evaluation of growth and neurodevelopment within the first 2 years of life.

STUDY DESIGN: Multi-centre observational prospective study.

STUDY POPULATION: Neonates meeting the criteria for surgical repair of CDH. In Rotterdam neonates meeting the criteria for surgical repair of EA can also be included in the study protocol.

INTERVENTION: Non-invasive neuromonitoring of CDH and EA neonates

PRIMARY STUDY PARAMETERS: Association between cerebral oxygenation and activity as evaluated perioperative by NIRS and aEEG and evaluation of growth and neurodevelopment within the first two years of age.

SECONDARY STUDY PARAMETERS: Changes in cerebral oxygenation and activity as evaluated by NIRS and aEEG and a comparison between open and minimal access surgery of the diaphragm defect. Arterial blood gas analysis, tissue oxygenation and transcutaneous CO2 measurements during surgery. Prenatal screening ultrasound results for CDH. Pre- and postoperative intensive care management such as ventilation settings, need of oxygen and use of
vasoactive medication, ventilator free days at day 28, postoperative pain scores every eight hours (COMFORT scores), length of hospital stay recurrence rate in the two years after

surgery
and cranial ultrasound pre- and postoperative and at discharge and 1 year old.

Doel van het onderzoek

Association between cerebral oxygenation and activity as evaluated perioperative by NIRS and aEEG and evaluation of growth and neurodevelopment within the first two years of age.

Onderzoeksopzet

During admission and at 6, 12, 18 and 30 months

Onderzoeksproduct en/of interventie

Neuromonitor perioperative by NIRS and aEEG

Contactpersonen

Publiek

Erasmus MC – Sophia Children’s Hospital, Dept. of Pediatric Surgery

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Surgical repair of the diaphragmatic and esophageal defect 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 15-04-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49066
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6972
NTR-old	NTR7160
CCMO	NL59526.078.17
OMON	NL-OMON49066

Resultaten