Comprehensive assessment of the long-term effects of necrotizing enterocolitis and its treatment

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To determine the long-term outcome after necrotizing enterocolitis during neonatal life, regarding (pain) sensitivity, sensory processing, behaviour, executive function, scar satisfaction (in surgically treated NEC patients), and (health-related)...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53387

Source
ToetsingOnline

Brief title
Long-term effects of necrotizing enterocolitis

Condition

- Other condition
- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease, intestinal inflammation and injury

Health condition

vroeggeboorte

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Vrienden van het Sophia

Intervention

Keyword: Long-Term Effects, Necrotizing Enterocolitis, Pain, Preterm Infants

Outcome measures

Primary outcome

This study has two primary endpoints: the between group difference in Short Sensory Profile score and the between-group difference in heat pain sensitivity.

Secondary outcome

In addition, we will assess the between-group differences in heat detection, cold detection, cold pain sensitivity, mechanical detection, mechanical pain sensitivity, behaviour, executive function, chronic pain, and (health-related) quality of life and we will assess cosmetic outcome of and satisfaction with the scar in surgically treated NEC patients.

Study description

Background summary

Emerging evidence suggests that exposure to pain or opioids during the neonatal period might have long-lasting effects. Rodent studies show that exposure to pain during the neonatal period affects brain development and induces long-term behavioural changes. Exposure to opioids in absence of pain also caused neurotoxic effects in rodent studies, whereas exposure to opioids in presence of pain mitigated these effects and may thus have a neuroprotective effect. In humans, exposure to pain in the neonatal intensive care unit (NICU) has been associated with changes in brain structure, impaired cognitive development and altered pain sensitivity. Contradictory effects of neonatal opioid exposure

have been found in humans, which may reflect differences in the balance between the exposure to pain and opioids. Since both exposure to pain and exposure to opioids could harm brain development, it is essential to get this balance right. A recent study in our NICU showed that despite analgesic therapy, the majority of necrotizing enterocolitis (NEC) patients experienced pain during the disease, which in some patients persisted for hours. Therefore, NEC patients may suffer negative long-term consequences of neonatal pain. On top of that, surgical treatment of NEC results in a scar and may thereby have long-term effects on cosmetic outcome and quality of life.

Study objective

To determine the long-term outcome after necrotizing enterocolitis during neonatal life, regarding (pain) sensitivity, sensory processing, behaviour, executive function, scar satisfaction (in surgically treated NEC patients), and (health-related) quality of life in children aged 6-15 years.

Study design

A cross-sectional cohort study comparing outcomes of children with a history of NEC with a gestational age- (GA), sex- and age-matched control group of preterm born children without a history of NEC. Both conservatively and surgically treated NEC patients will be included.

Study burden and risks

To our knowledge there are no medical risks associated with participation in this study.
Participants will be visited at home (or a nearby location of their choice) with the Sophia research bus, in order to minimize the logistical burden of participation. The study session will take approximately 1 hour. It will consist of Patient Reported Outcome Measurement to evaluate participants* general wellbeing, assessment of mechanical detection sensitivity using Von Frey filaments, assessment of mechanical pain sensitivity using a pressure algometer, and assessment of thermal detection and pain sensitivity using the Thermal Sensory Analyzer (TSA). These measurements are non-invasive and have all been performed previously in children (Blankenburg et al., 2010; Valkenburg et al., 2015; van den Bosch et al., 2017; Walker et al., 2009). The scar assessment in surgically treated NEC patients consists of evaluation of the cosmetic outcome by the researcher and evaluation of the patient*s satisfaction with the scar using the SCAR-Q questionnaire.
To ensure participants are at ease during the study procedure, they will be informed on forehand and will be asked to report their fear and pleasure during the breaks using the Wong-Baker Faces Rating Scale (Wong & Baker, 1988). The study is immediately terminated when the child gives a score of 5 (sad face on the faces scale) or if the parents or the researcher rate the child with a

score of 5. Children participating in a previous TSA study reported low Wong-Baker Faces Rating scores during the procedure, indicating that they considered it fun rather than frightening (van den Bosch et al., 2013) .
While the child performs the measurements, the child*s parent/caregiver will be requested to complete six questionnaires about their child: the Short Sensory Profile (SSP), the Child Behavior Checklist (CBCL), the Behavior Rating Inventory of Executive Function (BRIEF-2), the Chronic Pain Questionnaire (CPQ), the Pediatric Quality of Life inventory (PedsQL), and the Dutch-Child-AZL-TNO-Quality-of-Life (DUX-25). Completing these questionnaires takes approximately an hour and can be done during the study visit via an online portal, using an iPad which will be provided. Children aged 8 years or older will also be asked to complete the CPQ, PedsQL and DUX-25 themselves. They can do this before the study visit using the online portal. Completing these three questionnaires takes approximately half an hour.
Overall, we consider the risk associated with participation in this study negligible and the burden minimal. There are no benefits of participation to the participant himself/herself or his or her family, except that participants will receive a small gift. This research contributes important knowledge about the long-term effects of NEC and neonatal pain and aims to improve pain management for these vulnerable patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)

Inclusion criteria

NEC group: Preterm born children treated (surgically or conservatively) for necrotizing enterocolitis Bell*s stage II or III in the Erasmus MC-Sophia Children*s Hospital after January 1, 2008; Corrected age 6-15 years; Informed consent from parents/caregivers
Control group: Preterm born children admitted to the NICU of the Erasmus MC - Sophia Children*s Hospital after January 1, 2008; Corrected age 6-15 years; Informed consent from parents/caregivers

Exclusion criteria

NEC group: Focal intestinal perforation solely instead of NEC; Insufficient understanding of the Dutch or English language; Severe intellectual disability (defined as unable to cooperate in the performed tests); Severe motor disability (defined as unable to determine the child*s reaction time prior to the thermal sensitivity assessment)
Control group: In addition to the exclusion criteria mentioned above, diagnosis of necrotizing enterocolitis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-07-2023
Enrollment:	158
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2023
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	ID
CCMO	NL83621.078.23