The Microcirculatory Profile in Necrotizing Enterocolitis

Published: 23-07-2009
Last updated: 06-05-2024

To establish microcirculatory profiles using non-invasive diagnostic imaging in NEC.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON33444

Source
ToetsingOnline

Brief title
Microcirculatory Profile in NEC

Condition

- Gastrointestinal conditions NEC
- Neonatal and perinatal conditions

Synonym
inflammatory condition of the bowel

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: Microcirculation, NEC

Outcome measures

Primary outcome

The main study parameter is to determine the microcirculation and vascular reactivitiy in NEC.

Secondary outcome

Secondary study parameters are for example whether microcirculatory measurements can be used to predict which infants will need surgical intervention for NEC.

Study description

Background summary

Necrotizing enterocolitis (NEC) is a devastating gastrointestinal disease mainly affecting premature neonates with a relatively high mortality and morbidity. The microcirculation might play an important role in the pathogenesis. Limited studies have been performed using non-invasive radiological imaging tachniques to study the microcirculation in NEC.

Study objective

To establish microcirculatory profiles using non-invasive diagnostic imaging in NEC.

Study design

Single centre, observational, prospective cohort study.

Study burden and risks

Subjects will have no direct benefits of participating in this study. We aim to establish a microcirculatory profile as a non-invasive biomarker for the disease progress of NEC.
No adverse events have been reported using the different diagnostic imaging techniques (Sidestream Dark Field Imaging, Near Infrared Spectroscopy and Doppler Ultrasound). The expected burden for the participants is very low, all

techniques are non-invasive and no radiation is involved. The only possible burden could be that the measurements need to be performed daily and that some minor manipulation may be required to obtain qualitatively good images.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Group 1:
- All neonates with sustained feeding intolerance and/or suspected NEC.
Group 2:
- Neonates without suspected NEC, matched for gender and gestational age with participants from group 1.
Group 3:
- All neonates with congenital gastrointestinal pathology.

For all groups: informed consent.

Exclusion criteria

- Severe cardiac anomaly
- Severe respiratory anomalies
- Severe anomalies of the central nervous system

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2009
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2009
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	NL26661.078.09