Circulation in the smallest vessels in neonates suspected of necrotizing enterocolitis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23436

Source
NTR

Brief title
Microcirculation & NEC

Health condition

Necrotizing enterocolitis (NEC). In Dutch: necrotiserende enterocolitis.

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

To determine the microcirculatory profile in infants with persistent feeding intolerance or suspected NEC. We would like to determine whether NEC is associated with a regional decreased microcirculation.

Secondary outcome

1. To determine whether microcirculatory measurements can be used to predict which infants will need surgical intervention for NEC;

2. To quantify the mesenteric arterial circulation during laparotomy using SDF and to correlate these values with the ones obtained prior to surgery;

3. To determine the correlation between microcirculatory and macrocirculatory measurements (RR);

4. To evaluate mesenterial vascular responses by in vitro pharmacology and especially focus on the role of NO and his products;

5. To evaluate whether surgical intervention improves microcirculation.

Study description

Background summary

The microcirculation might play an important role in the pathogenesis of necrotizing enterocolitis. We would like to determine the microcirculatory profile using different techniques (SDF, NIRS and Doppler) and perform basic scientific research to evaluate the mesenteric vascular response.

Study objective

The microcirculatory profile is altered in infants with NEC.

Study design

Neonates from group 1 and 2 will be followed for 7 consecutive days.

In case of an operative procedure for neonates in group 1, intra-operative measurements will be performed and for 3 days following surgery. Infants from group 3 will be used as control patients for the intra-operative measurements.

Intervention

This is an observational study. The following techniques will be used to monitor the microcirculatory profile in the groups described in inclusion criteria:

1. Sidestream darkfield imaging (SDF): non-invasive assessment microcirculation;

2. Near infrared spectroscopy (NIRS): non-invasive measurement of tissue oxygenation;

3. Doppler: flow velocity of superior mesenteric artery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Group 1: All neonates suspected of NEC or severe feeding intolerance;

2. Group 2: Control patients for group 1, matched for gender and age;

3. Group 3: neonates with congenital gastrointestinal pathology, ie atresia, gastroschisis, omphalocele.

Exclusion criteria

Severe cardiac and respiratory anomalies.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2009
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-08-2009
Application type:	First submission

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
NTR-new	NL1840
NTR-old	NTR1951
Other	METC Erasmus Medical Center : MEC-2009-198
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A