After NEC

No registrations found.

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

Summary

ID

NL-OMON22150

Source
NTR

Brief title
NaNEC

Health condition

necrotizing enterocolitis

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: RUG

Intervention

Outcome measures

Primary outcome

Our main study parameters are based on the following questions:

- Intestinal oxygen saturation (and extraction) measured with NIRS and the time it takes to reach full enteral feeding after developing NEC

- The measurement of urinary I-FABPs and the time it takes to reach full enteral feeding after developing NEC

- The measurement of plasma citrulline and the time it takes to reach full enteral feeding after developing NEC

Our main study parameters consist of:

- Intestinal oxygen saturation (rintSO2)

- Intestinal FTOE

- Concentration of urinary I-FABP

- Plasma Citrulline levels

Secondary outcome

Our second objective is to assess the relation between the time it takes to reach full enteral feeding (more or less than 10 days) after developing NEC and neurodevelopmental outcome measured with the assessment of the quality of GMs (and the calculation of the motor-optimality score) at the term and three months post term age.

The study parameter to answer our second objective is:

- Quality of general movements (motor-optimality score)

Study description

Study objective

Intestinal tissue oxygen extraction, IFABP levels and plasma citrulline levels relate to time to full enteral feeding after Necrotizing Enterocolitis in preterm infants

Study design

NA

Intervention

none: observational

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Infants with a gestational age <37 weeks with confirmed pneumatosis intestinalis on x-ray, or suspected NEC > Bells stage 1, admitted on the NICU in Groningen.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Large chromosomal abnormalities

- Intraventricular hemorrhage/Perventricular hemorrhage >grade 2

- Use of dexamethason

- Congenital heart deformities other than patent ductus arteriosus

- Abdominal wall defects/other congenital gastroenteral deformities (ie atresia, microcolon)

- Parents/caretakers who are unable to understand Dutch or English

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-09-2014
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	NL4664
NTR-old	NTR4816
Other	: METc2014/283

Study results