

CALIFORNIA trial

No registrations found.

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

Summary

ID

NL-OMON22270

Source

NTR

Brief title

CALIFORNIA trial

Health condition

Necrotising enterocolitis
Near Infrared Spectroscopy (NIRS)
Faecal microbiota
Biomarkers
Gut wall integrity
Bile acids

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

The development of necrotising enterocolitis as determined by an independent paediatric radiologist (pneumatosis intestinalis on abdominal x-ray) or by surgeon during surgery

Secondary outcome

Urinary i-FABP/creatinin ratio, urinary 8-OHdG/creatinine ratio, urinary F2-IsoP/creatinin ratio, faecal Calprotectin and faecal bile acids, gene-expression (ao.TLR-4) on shedded enterocytes in the faeces, GLP1/2 in plasma, bile-acids in plasma, and regional tissue oxygenation measured by abdominal/cerebral NIRS.

Study description

Background summary

Rationale: Necrotizing enterocolitis (NEC) is the most frequent, often life threatening, gastrointestinal disease in neonates. Mortality can reach 40%, and both short and long term morbidity are significant. Its cause is yet unknown. The risk of developing NEC is inversely related to gestational age and birth weight. Other risk factors for NEC are cardiovascular disorders associated with decreased intestinal circulation and maternal tocolysis with NSAIDs. However, it is not possible yet to identify neonates who will ultimately develop NEC. Identification of these patients is the key in both prevention and early treatment of NEC.

Objective: To identify non-invasive markers for NEC in neonates at risk to develop this disease.

Study design: prospective cohort study

Study population: 100 consecutive neonates considered to have risk factors for NEC, i.e. gestational age \geq 30 weeks, birth weight \geq 1000 gram, gestational age \geq 32 weeks and birth weight \geq 1200 gram, antenatal exposure to NSAIDs, cardiovascular disorders associated with decreased intestinal circulation.

Intervention (if applicable): There are no interventions

Main study parameters/endpoints:

Study parameters: urinary Intestinal Fatty Acid Binding Protein (I-FABP) to Creatinine ratio, urinary 8-hydroxy-2'-deoxyguanosine (8-OHdG) to creatinine ratio, urinary F2-isoprostanes

(F2-IsoPs) to creatinine ratio, faecal Calprotectin, faecal bile acids, faecal microbial analysis, gene expression (e.g. TLR-4 on shedded enterocytes in the faeces), plasma levels of Glucagon Like Peptide-1,2 and bile acids, Near Infrared Spectroscopy (NIRS) of abdomen and cerebrum. Endpoint: the development of NEC as demonstrated radiologically (defined as the presence of pneumatosis intestinalis on an abdominal X-ray, diagnosed by an independent paediatric radiologist) or diagnosed during surgery.

Study objective

We hypothesize that before clinical manifestation of NEC, urine I-FABP, serum GLP1/2, faecal Calprotectin, faecal TLR4 (on shedded enterocytes) and faecal bile acids can be used as predictive markers for NEC.

We also hypothesize that Near Infrared Spectroscopy is able to identify neonates at high risk for NEC by early identification of decreased bowel oxygenation.

Finally we hypothesize that the faecal microbiota is different in high risk neonates who develop NEC versus those who do not.

Study design

Collection/measurement Day
(until development of abdominal emergency
or
until NICU discharge
(with a maximum of 5 weeks))

Urine collection Day 1 postnatal afterwards three times a week

Faeces collection Day 1 postnatal afterwards two times a week

Blood collection - within first 7 days post-natal

- Cerebral and abdominal NIRS measurement Day 1 up to and including day 5 postnatal, day 8 + weekly

Intervention

none

Contacts

Public

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Eligibility criteria

Inclusion criteria

All children admitted to the neonatology department, which are

- born at a gestational age of <30 weeks or
- born with a birth weight of <1000 gram or
- born at a gestational age of <32 weeks and categorized as small for gestational age (birth-weight \leq 1200 gram) or
- born with a cardiovascular disease resulting in a possibly reduced splanchnic bloodflow (e.g. aortic coarctation, heart disease with ductal dependent systemic circulation) or
- antenatal exposed to NSAIDs (after maternal tocolysis with Indomethacine)

Exclusion criteria

Other abdominal diseases, e.g. abdominal wall defects or congenital intestinal atresias

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:	Recruiting
Start date (anticipated):	05-10-2012
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion	
Date:	27-08-2013
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	NL3981
NTR-old	NTR4153
Other	ABR : 39302.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A