CALIFORNIA trial

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22270

Bron
Nationaal Trial Register

Verkorte titel
CALIFORNIA trial

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 ¡Ü 30 weeks, birth weight ¡Ü 1000 gram, gestational age ¡Ü 32 weeks and birth weight ¡Ü 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, genexpression (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.

Doel van het onderzoek

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.

Onderzoeksopzet

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 7days post-natal

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

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 ¡Ü 1200 gram) or

- born with a cardiovascular disease resulting in a possibly reduced splanchnic bloodflow (e.g. aortic coarcation, heart disease with ductal dependent systemic circulation) or

- antenatal exposed to NSAIDs (after maternal tocolysis with Indomethacine)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2012
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3981

Register	ID
NTR-old	NTR4153
Ander register	ABR : 39302.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A