

BOND study

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Preterm infants are at risk for neurodevelopmental impairment, but also for obesity and risk factors of cardiometabolic diseases. Nutrition in the early neonatal phase and altered early growth might be predisposing these risks. Early body...

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

Samenvatting

ID

NL-OMON24016

Bron

NTR

Verkorte titel

BOND study

Aandoening

Body composition (fat mass, fat free mass)

Preterm infants

Brain

Growth

Lichaamssamenstelling (vetmassa, vetvrije massa)

Te vroeg geboren kinderen

Hersenen

Groei

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia Children's hospital

Overige ondersteuning: Erasmus MC - Sophia Children's hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Body composition (percentage fat mass and fat-free mass) measured using air-displacement plethysmography and neurodevelopmental outcome assessed using Bayley Scales for Infant and Toddler Development, third edition and eye-tracking at 2 years corrected age.

Toelichting onderzoek

Achtergrond van het onderzoek

This observational non-invasive study, conducted in a level IV NICU in Rotterdam, the Netherlands, aims to elucidate the association between body composition and neurodevelopmental outcome up to two years of age in preterm born infants.

Doel van het onderzoek

Preterm infants are at risk for neurodevelopmental impairment, but also for obesity and risk factors of cardiometabolic diseases. Nutrition in the early neonatal phase and altered early growth might be predisposing these risks. Early body composition is considered a proxy for long-term metabolic health and may be associated with brain development.

This study aims to elucidate the association between neurodevelopmental outcome and body composition. We hypothesize fat mass and fat free mass are associated with neurodevelopmental outcome at two years of age in preterm born infants.

Onderzoeksopzet

NICU stay, term corrected age, 6 weeks, 6 months, 1 year and 2 year corrected age.

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Preterm infants born before 30 weeks of gestation who are admitted to the NICU of the Erasmus MC within 48 hours after birth.

Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe congenital and chromosomal anomalies
2. Perinatal asphyxia (defined as 5'min APGAR score below 5 and cord blood pH below 7.00)
3. Severe brain injury (defined by intraventricular hemorrhage grade III or IV, venous infarction or periventricular leucomalacia gr II or higher)
4. Post hemorrhagic ventricular dilatation requiring lumbal punctures
5. Congenital TORCHES infections

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 14-09-2014
Aantal proefpersonen: 150
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 02-08-2016
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

NTR-new

ID

NL5757

Register

NTR-old

Ander register

ID

NTR6024

: MEC-2014-379

Resultaten