

BOND study

No registrations found.

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

Summary

ID

NL-OMON24016

Source

NTR

Brief title

BOND study

Health condition

Body composition (fat mass, fat free mass)

Preterm infants

Brain

Growth

Lichaamssamenstelling (vetmassa, vetvrije massa)

Te vroeg geboren kinderen

Hersenen

Groei

Sponsors and support

Primary sponsor: Erasmus MC - Sophia Children's hospital

Source(s) of monetary or material Support: Erasmus MC - Sophia Children's hospital

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Body composition and brain growth assessed using cranial ultrasound or MRI and head circumference measurement at term equivalent age, 6 weeks and 6 months corrected age. Potential factors influencing the interaction between the brain and the gut (gut-brain axis): nutrition (enteral and parenteral nutrition, breastfeeding), feces (microbiome), saliva (microbiome, cortisol, ghrelin and leptin), hair (cortisol). Statistical adjustment for lifestyle factors (questionnaires) and clinical parameters.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

not applicable

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 14-09-2014

Enrollment: 150

Type: Anticipated

Ethics review

Positive opinion

Date: 02-08-2016

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

NTR-new

ID

NL5757

Register

NTR-old

Other

ID

NTR6024

: MEC-2014-379

Study results