# Body composition and neurodevelopment in preterm infants

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | - |

## Summary

### ID

NL-OMON21514

**Source**
NTR

**Brief title**
BOND

**Health condition**

preterm infants
body composition
neurodevelopmental outcome
nutrition

### Sponsors and support

**Primary sponsor:** Erasmus MC - Sophia Children's Hospital
**Source(s) of monetary or material Support:** ?

### Intervention

### Outcome measures

**Primary outcome**

Body composition (percentage body fat) at 2 years corrected age
Neurodevelopmental outcome assessed by Bayley Scales of Infant and Toddler Development

(mental and motor outcome measures) and eye-tracker at 2-years corrected age

### Secondary outcome

Body composition at term-equivalent age, 6-weeks, 6-months corrected age.

Brain growth at 6-weeks corrected age.

Microbiome at 2-years corrected age.

Blood pressure at 2-years corrected age

## Study description

### Background summary

This is a single-center ongoing, longitudinal observational cohort study conducted in the Netherlands. The aim of the study is to assess the association between body composition, as proxy of metabolic health, and neurodevelopmental outcome in preterm infants born before 30 weeks of gestation. Preterm infants are followed-up until the corrected age of 2 years with regular visits including body composition measurements, other markers of metabolic health and assessment of brain growth and neurodevelopmental outcome

### Study objective

Early nutrition in preterm infants is essential for growth and neurodevelopment. The last decades more aggressive nutrition has been implemented in clinical practice to ensure optimal growth and thereby optimal neurodevelopmental outcome, as previous cohort studies showed that catch-up growth is associated with an improved neurodevelopmental outcome. However, it has also been shown recently that catch-up growth is associated with obesity and non-communicable diseases already in childhood. No studies assessed the influence of early growth and early nutrition on body composition in preterm infants in relation to neurodevelopmental outcome. We hypothesize that catch-up growth in the early postnatal period results in increased neonatal and childhood fat mass, but not in improved neurodevelopmental outcome.

### Study design

Follow-up at: term-equivalent age, 6 weeks, 6 months, 1 year and 2 years corrected age

### Intervention

not applicable - observational trial

# Contacts

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# Eligibility criteria

## Inclusion criteria

Preterm birth < 30 weeks of gestation

Admission to NICU within 48 hours after birth

Written informed consent

## Exclusion criteria

Severe brain injury (IVH gr III/IV, post-hemorrhagic ventricular dilatation)

Perinatal asphyxia (pH < 7.00 and 5' min APGAR score <5)

Congenital TORCHES infection

Chromosomal abnormalities

Severe congenital anomalies

# Study design

## Design

**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: | 21-07-2016 |
| 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 | ID |
|---|---|
| NTR-new | NL5831 |
| NTR-old | NTR5985 |

| Register | ID |
| --- | --- |
| Other | : MEC-2014-379 |

# Study results

**Summary results**
not applicable