Body composition and neurodevelopment in preterm infants

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53045

Source
ToetsingOnline

Brief title
BOND

Condition

- Other condition
- Structural brain disorders
- Neonatal and perinatal conditions

Synonym
body composition, brain development

Health condition

groei en lichaamssamenstelling

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Body composition, Brain development, Preterm infant

Outcome measures

Primary outcome

Body composition measured by PEAPOD/BODPOD, defined by fat mass (FM, gram) and fat free mass (FFM, gram) using the BOD POD or DXA

Neurodevelopment measured using Bayley Scales of Infant and Toddler Development, third edition (Bayley-III-NL), at 2 years corrected age and Wechsler Preschool and Primary Scale of Intelligence, third edition (WPPSI-III-NL), general intelligence assessment at 5.5 years corrected age and Wechsler Intelligence Scale For Children (WISC-V-NL), general intelligence assessment at 8 years corrected age.

Secondary outcome

- Growth pattern
- Nutritional intake (enteral and parenteral)
- CUS measurements
- Neurodevelopment at 2 years corrected age (Bayley-III motor score, Lexi-list and CBCL 1,5-5), 3 years corrected age (BRIEF-P and CBCL 1,5-5), 5,5 years corrected age (M-ABC-2, BRIEF-P and CBCL 1,5-5) and 8 years corrected age (M-ABC-2, BRIEF-2 and CBCL 6-18, TRF 6-18, OBVL).

- Processing of visual stimuli (Eyetracker)

- Sleep and circadian rhythm

- Dental health status at 5.5 and 8 years corrected age

- Bone mineral density at 3, 5,5 and 8 years corrected age

- Parents* and patient reported quality of life (PedsQL and PROMIS 7+2) of

preterm born children at 8 years corrected age.

- Parents* needs in the neonatal follow-up program (qualitative research).

Study description

Background summary

Preterm infants are born in a critical period for both growth and brain development. It is well known that they are at increased risk for long-term growth failure and neurologic, developmental and cognitive impairment. Many preterm infants are growth restricted at hospital discharge, often caused by inadequate nutrional intake. This insufficient intake leads to protein and energy deficits early in life. Preterm infants are also known to have altered body composition. Both catch-up growth and (intra- or extra-uterine) growth restriction increase the risk of metabolic syndrome later in life, while only catch-up growth diminishes the risk of neurodevelopmental impairment. Recently, it has been shown that the amount of subcutaneous fat accretion is positively related to the quality of motor development. However, in contrast to these findings, a negative relationship has shown between visceral fat and brain volume.
Thus, it seems likely that nutrition and nutritional status are of great importance in growth, body composition and brain development of preterm infants. However, the relationship between body composition and development of the brain in preterm infants has not been investigated yet. While we think this is of great importance for feeding practices and development of the infant. We hypothesize that growth restricted infants have altered brain development compared to non-growth restricted infants, which is (partly) related to differences in body composition. Furthermore, very little is known about the dental- and bone development of children born preterm.
Taking all this above into account, it seems clear that preterm born children are at risk for multiple long-term complications, which can alter the quality of life. Value-based healthcare, focused on (not necessarily medical) outcomes that are relevant for the patients and their families is trending. Therefore,

we will assess the quality of life of preterm born children aged 8 years (according to themselves and their parents). Furthermore, parents will be asked to evaluate the items of the standard ex-NICU follow-up protocol and the BOND study for transition to value-based healthcare for the neonatal follow-up protocol, since it is important and needed taking parents* perceptions into account.

Study objective

Our main objective is to explore the relationship between nutritional intake, growth, body composition and brain development. Hereby we want to improve our knowledge about how to feed the preterm infant in a way that contributes to a better cognitive development and a decrease in the risk of developing metabolic syndrome.

Study design

Observational, cohort study

Study burden and risks

The burden and risk of this study is expected to be minimal. During hospital stay in the neonatal period no assessments will be performed. Data will be obtained about growth, nutritional intake and neonatal course. Brain development will be assessed using standard care MRI scans and cranial ultrasound. Both parents will be asked to fill out a short questionnaire (10 minutes) during hospital stay about lifestyle and pregnancy. Parents will be asked to keep record of changes in feeding practices and to note the exact intake 3 days twice until the corrected age of 6 months.

Preterm infants are routinely assessed at the outpatient clinic and nearly all of our study measurements will be done at those visits. Only the assessments at the age of 3 (and possibly 8) years old requires an extra hospital visit; if parents agree to this extra visit, their travel expenses will be compensated.

At these routine follow-up visits, body composition will be measured repeatedly in the PEAPOD and BODPOD. The PEAPOD and BODPOD are non-invasive and quick methods for measuring body composition. The PEAPOD proved to be safe for measuring preterm infants.
Once a cranial ultrasound will be performed, which will be done while the infant is comfortable/asleep, lying with his parents. This measurement will take less than 5 minutes.
The other assessments at 2, 3, 5 and 8 years corrected age are all non-invasive, safe, most of them are performed at home, at a time convenient for the parents and are little burden to the parents and the child. At 8 years of age, the children fill in 1 short questionnaire themselves. At 5.5 and 8

years corrected age ca, dental health status will be examined through a pediatric dentist.

The assessments will be performed by dedicated people who are familiar with this specific patient population. The infants included in this study will not directly benefit from participation in this study. However, if we are able to identify the influence of growth pattern, and thereby nutritional requirements, on body composition and brain development, it will help us to provide the most optimal outcome for preterm infants in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Premature infants born before 30 weeks of gestation and admitted to the neonatal intensive care unit, Erasmus MC-Sophia Children's Hospital, Rotterdam,

the Netherlands

Exclusion criteria

Severe congenital en/of chromosomal abnormalities
Asfyxia (defined by cord blood or (if absent) first postnatal pH < 7.0)
Intraventricular hemorrhage grade III/IV
Posthemorrhagic ventricular dilation requiring lumbal punctures
Congenital (TORCHES) infection (Toxoplasmosis, Rubella, CMV, Herpes, Hepatitis, Coxsackie, Syphilis, Varicella Zoster, HIV, Parvo B19)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-11-2022

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL48502.078.14