Biomarkers for outcome at school age in preterm born children

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational invasive

Summary

ID

NL-OMON50419

Source
ToetsingOnline

Brief title
BIOS study

Condition

- Congenital and peripartum neurological conditions
- Neonatal and perinatal conditions
- Cognitive and attention disorders and disturbances

Synonym
brain damage, White matter injury

Research involving
Human

Sponsors and support

Primary sponsor: Neonatologie, Wilhelmina Kinderziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain development, Neuroinflammation, Preterm children, School age outcome

Outcome measures

Primary outcome

The main study parameters are intelligence quotient and GFAP (a neuroinflammatory marker).

Secondary outcome

The secondary study parameters are mismatch negativity (derived from EEG) and presence of behavioral disorders and virtual reality parameters indicating level of cognitive skills in a more dynamic and interactive simulated environment.

Study description

Background summary

Extremely preterm born infants (gestational age <28 weeks) are at increased risk for cognitive and behavioural impairments at school age. We hypothesize that early insults on brain maturation pervasively impact development, alter essential neurodevelopmental sequences and thereby comprise building blocks for higher cognitive functioning.

Study objective

The objective of the study is to identify biomarkers that associate to brain (physiological) status or mental (functional) health status and their interaction. More specific, our first aim is to determine the association between neuroinflammatory markers and mental health status. Our secondary aim is to determine the association between EEG phenotypes and mental health status.

Study design

Cohort study.

Study burden and risks

The burden of this study comprises of collection of a blood sample, faeces sample, hair and buccal swab, an MRI scan of the brain and a quantitative electroencephalography (EEG). These are study procedures on visit days for routine clinical care. No extra visits are needed for study procedures. Routine care and study procedures are specified in table 1 of the protocol (page 10).
On day 1, as part of the study procedure, a sample of 20 ml of blood will be collected. A topical anaesthetic (EMLA) can be used to minimise pain sensation. In addition, a faeces, hair and buccal swab sample will be collected and stored in a biobank. In addition, the Vineland interview will be conducted with the parents. Finally, an MRI scan will be made on this day and we will use a Virtual Reality (VR) shopping task to assess cognitive skills.
If on day one, behavioral or developmental problems are present, or parents/caregivers have concerns about behavior or development, the child will be referred to the child psychiatrist for extra behavioral assessments and treatment, if indicated. This is part of standard clinical care. We expect that a subpopulation of ~ 50% (i.e. n=64) of children will be referred.
On day 2, in addition to clinical care, the study procedure consists of a resting state EEG, and EEG tests (a hearing test, mismatch negative paradigm and a selective attention paradigm test).
Risks in participating in the study involve a small chance to develop a hematoma after venepuncture. The faeces, hair, and buccal swab sample collection and the MRI and EEG are non invasive procedures that pose no specific burden to the participants. Overall, risks are expected negligible and the burden is expected to be minimal. On the MRI scan, incidental findings may be noticed. If medical treatment for these findings is indicated, the subjects will be notified. If parents do not want to be informed about these findings, children cannot participate. Clinically relevant abnormalities warrant routine clinical care at the department of neonatology or psychiatry.

Contacts

Public
Selecteer

Lundlaan 6
Utrecht 3584 EA
NL
Scientific
Selecteer

Lundlaan 6
Utrecht 3584 EA

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Born between January 2007 and December 2012.
Gestational age <28 weeks.
Age at assessment: 7-11 years.

Exclusion criteria

Major chromosomal and/or congenital anomalies.
Inability to comply with the study procedures.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2018
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	27-12-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-02-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-03-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL59105.041.17

Study results

Date completed:	16-01-2023
Actual enrolment:	118