

# Functional and structural brain development in extremely preterm infants

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON46545

### Source

ToetsingOnline

### Brief title

early brain activity and brain development

### Condition

- Neonatal and perinatal conditions

### Synonym

preterm brain development/brain growth; preterm EEG/preterm brain activity

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Neonatologie

**Source(s) of monetary or material Support:** ESPR

## Intervention

**Keyword:** brain development, EEG, neonatal brain

## Outcome measures

### Primary outcome

Main study parameters/endpoints: the main study parameters are: the individuation of the principal EEG parameters able to predict brain development and long term outcome in extremely preterm infants.

### Secondary outcome

n.a.

## Study description

### Background summary

Survival of extremely preterm infants (born  $\leq 28$  weeks of gestation) has improved over the last decades, but the high incidence of abnormal neurodevelopmental outcome remains a reason for concern. The origin of brain impairment in preterm infants, may be found in the last trimester of gestation. This critical period for brain development, is spent in the neonatal intensive care unit, where infants are ventilated for respiratory distress, often experiencing hemodynamic instability and infections. Early and non-invasive prediction of neurodevelopmental outcome, using specific and reliable biomarkers for brain development, will be of outmost importance for clinicians to improve short and long term outcome in this vulnerable population. We hypothesize that early and repeated EEG brain monitoring, may be predictive of 1) later brain maturation and microstructure, assessed using conventional MRI and diffusion tensor imaging (DTI), 2) later brain function assessed with resting-state functional MRI (rsfMRI), and 3) long-term neurodevelopmental outcome.

### Study objective

The main objectives are: to determine whether early and serial EEG brain monitoring, is a bedside biomarker for later structural brain maturation and microstructural brain development and to examine whether serially EEG-measured brain function is related to subsequent resting-state functional MRI (rsfMRI)

data. The secondary objective is to investigate the relation between the most relevant brain function parameters, predicted by EEG, and long-term neurodevelopmental outcome in extremely preterm infants.

## **Study design**

Study design: Prospective observational cohort study

## **Study burden and risks**

The population of neonates who are likely to participate in this clinical investigation are high risk, intensive care patients but there are no additional risks envisaged with their participation in the Clinical Investigation. The risk analysis will be updated (if necessary) during the Clinical Investigation. The study can only be done using extremely preterm born patients since we want to investigate brain development and the risks linked to preterm birth.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

- born at the Wilhelmina children hospital <28 weeks corrected gestational age
- consent signed from parents of day 1 after birth

### Exclusion criteria

- congenital malformations
- suspected or proved genetic disorders
- suspected or proven metabolic diseases
- no parental/guardian consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 10-05-2019

Enrollment: 120

Type: Actual

## Ethics review

Approved WMO

Date:	28-11-2018
Application type:	First submission
Review commission:	METC NedMec

## 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	NL65406.041.18