# Safeguarding the brain of our smallest children ;* an investigator-initiated randomised, blinded, multinational, phase II feasibility clinical trial on near-infrared spectroscopy monitoring combined with defined treatment guidelines versus standard monitoring and treatment as usual in premature infants

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37782

**Source**
ToetsingOnline

**Brief title**
SafeBoosC

## Condition

- Neurological disorders NEC
- Neonatal and perinatal conditions

**Synonym**
cerebral hypoxia; cerebral oxygenation

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Region Hovestaden, Department of Neonatology 5024, Rigshospitalet
**Source(s) of monetary or material Support:** Danish Council for Strategic Research (DSF) under the Preparation of International Application (START)

## Intervention

**Keyword:** cerebral oxygenation, near infrared spectroscopy, neurodevelopmental outcome, preterm infant

## Outcome measures

### Primary outcome

The primary outcome is the burden of hypo- and hyperoxia in %hours during the

first 72 hours after birth.

### Secondary outcome

The secondary outcomes are brain activity on an amplitude-integrated

electroencephalogram (aEEG), blood biomarkers (brain fatty acid binding protein

(BFABP), neuroketal, and S100*), serious adverse reactions (SARs), severe brain

injury, and all cause mortality at term date (approximately three months after

birth). The exploratory outcomes are burden of hypoxia, burden of hyperoxia,

neonatal morbidities, brain injury score on magnetic resonance imaging (MRI),

number of therapies implemented during the intervention, physiological

variables (mean blood pressure (BP), pulse oximeter oxygen saturation (SpO2),

and partial pressure of carbon dioxide (pCO2)), and psychomotor impairment

according to neurodevelopmental scales at 24 months after term equivalent age

(BSIDIII)

# Study description

### Background summary

25,000 infants are born extremely preterm every year in Europe. This group of infants carries a high risk of death and subsequent cerebral impairment for the infant, especially in the first 72 hours of life. Mortality is about 20%, and about 25% of survivors live with either cerebral palsy or low intelligence quotient. Preventative measures are keys to reducing mortality and morbidity in this population. There is evidence that the cerebral oxygenation time spent out of range (time with hypoxia or hyperoxia) is associated with poor outcome in infants. Near-infrared spectroscopy (NIRS) has been used to monitor tissue oxygenation since the mid-1980s, and quantification of oxygenation in a percentage from 0 to 100% has been possible for 10 years. Still, there are no clinical trials and thus no solid evidence of the clinical utility of NIRS in preterm infants. Thus, research on the benefits and harms of cerebral monitoring using NIRS as a part of clinical management of premature infants is much needed. This study is , anticipatory on a large multi-center trial, a feasability trail in which 150 patient from 12 European neonatal centers will be included.

### Study objective

The primary objective of the SafeBoosC trial is to examine if it is possible to stabilise the cerebral oxygenation of extremely preterm infants (gestational age < 28 wks) during the first 72 hours of life through the application of cerebral NIRS oximetry and implementation of a set of defined clinical treatment guidelines (Appendix A protocol). We hypothesise that by using the specified treatment guidelines to respond to cerebral monitoring readings outside the target range, we would reduce the burden of hypo- and hyperoxia and consequently reduce brain injury.

### Study design

Preterm infants with a gestational age < 28 weeks will be randomised into one of two groups (experimental or control) after parental informed consent. Common is that both groups will have a cerebral oximeter monitoring device placed within three hours after birth.In the experimental group, the cerebral

oxygenation reading is visible, and the infant will be treated accordingly using a defined treatment guideline (Appendix A). In the control group, the cerebral oxygenation reading is NOT visible, and the infant will be treated as usual. 150 infants from 12 European neonatal units will be included in these phase II feasibility trial.
Cerebral monitoring with NIRS (standard care on our unit) will start within three hours of age and the study will last until 72 hours after birth, as these are the most critical. Each neonate will be followed up until (regular cranial ultrasound) and at the term equivalent age (advanced MRI) date (approximately after 3 months) and 24 months after the term equivalent age (Bayley Scales of Infant Development III (BSIDIII). During the first 72 hours of life also amplitude integrated EEG (aEEG; standard care on our unit) and at 6 and 64 hours after birth 1ml of blood and urine will be collected for determing levels of cerebral biomarkers (brain fatty acid binding protein; neurketal and S100beta).

**Intervention**

The premature infants will be randomised into one of two groups (experimental or control). Common is that both groups will have a cerebral oximeter monitoring device placed within three hours after birth. In the experimental group, the cerebral oxygenation reading is visible, and the infant will be treated accordingly using a defined treatment guideline (Appendix A protocol) . In the control group, the cerebral oxygenation reading is NOT visible, and the infant will be treated as usual.

**Study burden and risks**

The risks for participants are minimal; the monitoring, ultrasound investigations, MRI and follow up are already standard care on our unit. The blood sample on time point 6 and 64 hours after birth will be collected from an arterial line (standard care) and the amount of blood is small compared with the regular volumes of blood samples during the first days in these infants.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Children (2-11 years)

## Inclusion criteria

preterm, gestational age <28 weeks, inborn, egiligible for inclusion within 3 hours after birth

## Exclusion criteria

congenital malformation, outborn, postnatal age more than 3 hours, no informed consent

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Prevention

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-03-2013 |
| Enrollment: | 15 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 06-11-2012 |
| Application type: | First submission |
| 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 | NL39535.041.12 |

## Study results

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| Date completed: | 28-06-2016 |
| Actual enrolment: | 11 |

**Summary results**
Trial is onging in other countries