Invitation to participate

Mechanical ventilation of newborns with and without access to cerebral oximetry

A protocol for the SafeBoosC-IIIv investigator-initiated, pragmatic, open label, multinational randomised phase III clinical trial with parent-reported outcomes at 2 years of age

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SafeBoosC III
SAFEGUARDING THE BRAIN OF OUR SMALLEST CHILDREN

Objective

The objective of the SafeBoosC-IIIv trial is to evaluate the benefits and harms of cerebral oximetry in newborn infants on mechanical ventilation.

Inclusion criteria

- Gestational age more than 28+0 weeks
- Postnatal age less than 28 days
- Requiring mechanical ventilation by tracheal tube.
- Expected to receive mechanical ventilation for at least 24 hours
- Parental informed consent, unless the site has chosen to use 'opt-out 'or deferred consent as consent method.

Intervention

Cerebral oximetry started if possible before or, as soon as possible after mechanical ventilation has been initiated and continuing until the cardio-pulmonary function has been stabilised as evaluated by the attending physician, or until death. Cerebral oximetry will be used to modify clinical care to minimise cerebral hypoxia according to the **SafeBoosC-IIIv treatment guideline**.

Exclusion criteria

- Clinical suspicion of brain injury before initiation of mechanical ventilation (e.g. perinatal asphyxia)
- A cerebral oximeter is not available
- Newborns with congestive heart malformations in need of surgery.

Organisation

The Capital Region of Copenhagen is the sponsor and coordinating investigator and will cover all central costs. **We are at the time seeking funding.** Local costs, including staff, oximeters and if necessary, insurance must be organised locally or nationally

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Outcomes

There will be **two co-primary outcomes** assessed by a parental questionnaire at two years of age:

- a composite of death or moderate or severe neurodevelopmental impairment
- non-verbal cognitive score of PARCA-R

A minimal set of clinical secondary outcomes and severe adverse events reported after the first 28 days of life

Sample size

3000 infants must be randomized to demonstrate to detect a reduction of risk of death and moderate or severe neurodevelopment impairment from 20% to 15% between the experimental and control group.

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