

List of data needed for eCRF entry

| Version | Author(s) | Date | Changes | Approved by |
|---------|---------------------|----------|---|--------------|
| 1.0 | Mathias Lühr Hansen | 06.05.19 | Initial version | Gorm Greisen |
| 1.1 | Mathias Lühr Hansen | 05.09.19 | <ul style="list-style-type: none"> • Addition of data point “singleton or multiple birth” • Removal of “severe incidents due to monitoring” • Removal of “patent ductus arteriosus | Gorm Greisen |

Data needed at randomization

- Birth date and hour
- Gestational age in weeks
- Singleton or multiple birth
- Method of consent
- Decision to conduct full life support
- Time from birth until cerebral oximetry started (before or after 6 postnatal hours)

Data needed at 72 hours of age

- Gestational age in weeks and days
- Birth weight
- Gender
- Apgar 1 and Apgar 5
- Age in hours when cerebral oximetry was started
- Type of NIRS device used
- Visible cerebral oximetry monitoring (if control group participant)
- Cerebral oximetry monitoring stopped prematurely with reason
- Change of medical management due to cerebral hypoxia in patient record
- Surfactant therapy
- Cardiovascular support (volume, vasopressors, inotropes) before 72 hrs
- Parents discontinue from trial (yes/no) and reason if yes
- SARs

Data needed at 36 weeks of postmenstrual age (or referring to age at discharge home if that happened before 36 weeks)

- Follow-up data
- Major congenital anomaly
- SAEs
- Mechanical ventilation, and number of days of mechanical ventilation
- Sepsis

- Treatment for patent ductus arteriosus
- Cranial ultrasound performed before 8 days of age and/or after 35 days of age
- Intraventricular haemorrhage grade 3 or 4
- Cystic periventricular leukomalacia
- Post-haemorrhagic ventricular dilatation
- Cerebellar haemorrhage
- Cerebral atrophy
- Bronchopulmonary dysplasia
- Necrotizing enterocolitis stage 2 or greater via modified Bell's staging system or focal intestinal perforation
- Retinopathy of prematurity stage 3 or higher
- Death before 36 weeks post-menstrual age and before discharge to home
- Classification of cause of death
- Weight at follow-up and date for weighing