SafeBoosC-IIIv Steering Committee meeting

27 June 2024

Attendees: Mathias Lühr Hansen (CTU), Caroline Kamp (CTU), Johanne Juul Petersen (CTU), Janus Christian Jakobsen (CTU), Gorm Greisen (Denmark), Hans Fuchs (Germany), Gunnar Naulaers (Belgium), Renato Procianoy (Brazil), Jorge Fabres (Chile), Gabriel Dimitriou (Greece), Saudamini Nesargi (India), Eugene Dempsey (Ireland), Siv Fredly (Norway), Daniel Virella (Portugal), Livia Ognean (Romania), Merih Cetinkaya (Turkey), Jyoti Lakhwani (Zambia).

Moderator: Caroline Kamp
Minute taker: Johanne Juul Petersen

1) **Approval of the agenda**
   Agenda approved.

2) **New members of the Steering Committee**
   The new Steering Committee was formed and now includes: Gonzalo Mariani/Gabriel Musante (Argentina), Atul Malhotra/Himanshu Popat (Australia), Gerhard Pichler (Austria), Gunnar Naulaers (Belgium), Renato Procianoy (Brazil), Jakub Tkaczyk (Czech Republic), Jorge Fabres (Chile), Laishuan Wang (China), Gitte Hahn (Denmark), Olivier Baud (France), Hans Fuchs (Germany), Gabriel Dimitriou (Greece), Saudamini Nesargi (India), Eugene Dempsey (Ireland), Monica Fumagalli (Italy), Siv Fredly (Norway), Daniel Virella (Portugal), Tomasz Szcapa (Poland), Livia Ognean (Romania), Adelina Pellicer (Spain), Cornelia Hagmann (Switzerland), Merih Cetinkaya (Turkey), Anne Marie Heuchan (UK), Fernando Silvera (Uruguay), Lina Chalak (US), Jyoti Lakhwani (Zambia).

   Since the last meeting, many new members have joined the Steering Committee, so Caroline briefly presented the structure of the organization. The Executive Steering Committee will undertake day-to-day running of the trial, but the Steering Committee will make all decisions.

3) **Trial status**
   a. **Protocol**
      The protocol version 2.0 has been submitted to the Danish Research Ethics Committees as an amendment. Hopefully, this protocol will be approved in August.

   b. **Centers**
      43 centers have received an email with information on the next steps. When additional centers join, just send an email to Caroline, and they will receive information as well.

   c. **GCP plan**
      Copenhagen Trial Unit is working on a GCP plan. All centers will need a GCP person for monitoring. When it is ready, the GCP plan will be presented to the Steering Committee.

d. Training module

Copenhagen Trial Unit is currently updating the training module with the Executive Steering Committee. The training module will be available online and as a document. This will be presented to the Steering Committee when it is ready.

e. National Coordinator update

- **Gorm, Denmark:** Currently awaiting ethics approval and contact with OxyPrem. Randomization is expected to begin in November.
- **Gunnar, Belgium:** Currently awaiting ethics approval, GCP person, and monitors. Randomization is expected to begin between March and June 2025
- **Renato, Brazil:** Currently awaiting contact to OxyPrem.
- **Jorge, Chile:** Currently awaiting response from other centers.
- **Hans, Germany:** Currently awaiting response from other centers.
- **Gabriel, Greece:** Currently awaiting response from other centers and contact to OxyPrem.
- **Saudamini, India:** Three centers are expected to join, and randomization is expected to begin in the end of the year.
- **Eugene, Ireland:** Currently awaiting funding, contracts, and a national sponsor. Randomization is expected to begin between January and March 2025.
- **Siv, Norway:** Currently awaiting ethics approval.
- **Daniel, Portugal:** Randomization is expected to begin between January and March 2025. Expects to enroll three to six sites.
- **Livia, Romania:** Randomization is expected to begin in March 2025. Expects to enroll three to five sites.
- **Merih, Turkey:** Randomization is expected to begin in the beginning of 2025.
- **Jyoti, Zambia**: Currently recruiting centers.

4) Frequently asked questions

Caroline goes through the inclusion criteria, as this has come up during several meetings with principal investigators:

- Newborns with gestational age more than or equal to 28+0 weeks
- Postnatal age less than 28 days
- Expected to receive invasive mechanical ventilation for at least 24 hours, as judged by the physician intending to randomise (i.e., not including CPAP or BiPAP)

This will also be posted on the website, safeboosc.eu.

Renato asks for the exclusion criteria. The exclusion criteria are currently described as:

- Suspicion of or confirmed brain injury or disorder (e.g. perinatal asphyxia, cerebral haemorrhage, cerebral malformation, genetic or metabolic disease)
- Suspicion or diagnosis of congenital heart malformations likely to require surgery

These are not precise definitions, and it will ultimately be a decision of the physician. There was a discussion of the wording regarding the first exclusion criteria and ‘perinatal asphyxia’. It is decided to include major brain hemorrhage (grade 3 or 4) and severe

hypoxic-ischemic encephalopathy in the brackets as examples of exclusion criteria to guide the physician. The Executive Steering Committee will suggest a revised wording and then send it to the Steering Committee. The final version of the text will be included in the next amendment of the protocol (2.1).

5) **Any other business**

Daniel asks about NIRS monitoring if the infant is extubated and re-intubated during the index hospital admission. Randomization will only direct the use of cerebral oximetry during the first invasive mechanical ventilation episode.

Gorm asks about the status of the contracts. These have been sent out earlier this week.

Next Steering Committee meeting will be 28th of August 2024, 20:30 CEST.