

SafeBoosC-IIIv Steering Committee meeting

1 May 2024

Attendees: Mathias Lühr Hansen (CTU), Caroline Kamp (CTU), Johanne Juul Petersen (CTU), Janus Christian Jakobsen (CTU), Gorm Greisen (Denmark), Gabriel Dimitriou (Greece), Hans Fuchs (Germany), Jyoti Lakhwani (Zambia), Jakub Tkaczyk (Czech Republic), Saudamini Nesargi (India), Adelina Pellicer (Spain), Thomas Szczapa (Poland), Jorge Fabres (Chile).

Moderator: Caroline Kamp

Minute taker: Johanne Juul Petersen

1) Approval of the agenda

Agenda approved.

2) Establishment of the Steering Committee

Janus presented the new trial setup with a step 1 and step 2. Funding has been obtained from the Independent Research Fund to cover central monitoring at CTU for step 1. The primary outcome for step 1 is hospital-free days within 90 days from randomization, and the sample size is 1,610 participants.

Caroline presented the structure of the organization. The Executive Steering Committee is Caroline Barkholt Kamp (trial manager), Johanne Juul Petersen (alternate trial manager), Adelina Pellicer, Eugene Dempsey, Gitte Hahn, Gorm Greisen, Gunnar Naulaers, Janus Christian Jakobsen (sponsor).

The Steering Committee will be members of the Executive Steering Committee and National coordinators. The tasks for the Steering Committee will be:

- Overall conduct and quality of the trial.
- Design of protocol and approval of amendments.
- Participating in steering group meetings.
- The decision-making body (e.g., trial extension or discontinuation, authorship, ancillary studies).

The tasks for the national coordinator:

- Enrolment of NICUs.
- Translate parental information and consent forms and obtain ethical approval for own NICUs first.
- Organize national network.
- Support, follow-up, participate in hiring and firing.

The following agrees to function as National Coordinators and as part of the Steering Committee: Gabriel Dimitriou (Greece), Hans Fuchs (Germany), Jyoti Lakhwani (Zambia), Jakub Tkaczyk (Czech Republic), Saudamini Nesargi (India), Adelina Pellicer (Spain), Thomas Szczapa (Poland), Jorge Fabres (Chile).

Due to a national holiday, not all possible national coordinators were able to join the meeting. The full Steering Committee will be established when we have contacted the remaining names on the list of possible national coordinators. We will add Uruguay to the list, which Adelina has contact information on. If any other countries wish to join later, this will be decided by the Steering Committee.

3) SOP for assessment of the primary outcome

Caroline presented the SOP for assessment of the primary outcome. Everyone agrees that the proposed assessment is possible. Other methods for contacting parents are suggested (e.g., e-mail or WhatsApp). Some means of communication are not safe enough for medical information in certain countries. Each center is responsible for their own blinding, the method can be individualized, if it has been approved by the Trial Manager.

We will add e-mail as mean of communication to the SOP.

4) Author qualification

Caroline presented a suggestion for author qualification: The Steering Committee will ultimately decide on authorships. A rule of thumb:

- National coordinator: 1 authorship.
- Centers: 1 authorship per 10 randomized infants per year.

No one has any objections to this.

5) Screening log

Gunnar suggested a simple screening log. This was not used in SafeBoosC-III, but in SafeBoosC-II. Everyone agrees that a screening log is needed. The screening log would need to capture any bias in selection in participants and could include gestational age (more or less than 34 weeks), surgery (yes/no) weight group, and sex. However, the data cannot be specific enough for the screened newborns to be identified.

The Executive Steering Committee will work out a proposal for a screening log and send it to the Steering Committee for comments and approval.

6) Any other business

Hans Fuchs has a concern regarding the consent form, as this should include approval for contact for a follow-up study (two years follow-up). This is already the plan, and the relevant forms are currently under development.

We will send out the following: Slides from the meeting including the list with names of national coordinators, protocol, SAE definitions, and SOP for assessment of primary outcome.