SafeBoosC-IIIv Steering Committee meeting

21 May 2026

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gabriel Dimitriou (Greece), Georg Schmölzer (Canada), Saudamini Nesargi (India), Paulina Toso (Chile), Hans Fuchs (Germany), Gerhard Pichler (Austria), Laishuan Wang (China).

Apologies: Adelina Pellicer (Spain), Renato Procianoy (Brazil), Mathias Lühr Hansen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Livia Ognean (Romania), Tomasz Szczapa (Poland), Merih Cetinkaya (Türkiye), Gitte Hahn (Denmark), Cornelia Hagmann (Switzerland), Jorge Fabres (Chile).

Absent: Jakub Tkaczyk (Czech Republic), Gabriela Trindade (Brazil), Lina Chalak (US), Monica Fumagalli (Italy), Eugene Dempsey (Ireland), Gunnar Naulaers (Belgium), Gabriel Musante (Argentina), Himanshu Popat (Australia), Jyoti Lakhwani (Zambia).

Moderator: Caroline Kamp
Minute taker: Johanne Juul Petersen

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

2) **Members of the Steering Committee**
   Caroline presented the current members of the Steering Committee—no changes since the last Steering Committee meeting.

3) **Central updates**
   Caroline gave an update on the central steps.

   - **Randomisation**
     17 centres have started randomisation in six countries. Six additional centres are ready to randomise. 238 participants have been randomised. 46 additional centres are interested in joining the trial across 22 countries and six continents in total. Currently, the predicted time until randomisation is completed in 3.4 years.

   - **Step two**
     Caroline explained that we are preparing for step two and currently applying for funding to cover central costs.

4) **National Coordinator update**
   Many centres are making significant progress, as reflected in the Trial Preparations Log (available on the website).

- **Georg, Canada**: The contract is done, and ethics approval has been obtained. Currently working on the staff training. Open to participate in step two. No regular follow-ups at 2 years of age, but solutions are possible.
- **Gabriel, Greece**: Five centres are randomising. One centre has issues with the ethics committee, but is in contact with Gabriel to resolve this. Open to participate in step two with regular follow-ups at two years of age.
- **Saudamini, India:** One centre is randomising, and one centre is ready to randomise. The next two centres are expected to be randomised within a month. Open to participate in step two. Follow-up options at two years of age are limited.
- **Hans, Germany:** Received minor comments from the ethics committee. Expect to begin randomisations within a few weeks following training and description of blinding procedure. Open to participate in step two with regular follow-ups at two years of age.
- **Paulina, Chile**: Currently working on recruiting centres. Afterwards, they will continue with the ethics committee. Open to participate in step two. No regular follow-ups at 2 years of age, but solutions are possible.
- **Gerhard, Austria:** Two centres are randomising. Open to participate in step two. No regular follow-ups at 2 years of age, but solutions are possible.

5) Substudies

A substudy meeting was held last month. Kosmas Sarafidis presented a substudy on cerebral oximetry for frequency of early cardiovascular interventions. The final protocol will be shared with the Steering Committee shortly.

Two substudies are currently ongoing:

- **Substudy on renal outcomes – Saudamini Nesargi**
  17 centres are currently participating in the substudy on renal outcomes.

- **Substudy on hypocapnia – María Carmen Bravo**
  13 centres are currently participating in the substudy on hypocapnia.

A new substudy was proposed, which was also presented at the substudy meeting:

- **Substudy proposal on environmental impact**
  Johanne Juul Petersen presented a substudy on the environmental impact of treatment guided by cerebral oximetry versus usual care. Johanne outlined the primary outcome, inclusion and exclusion criteria, and methods. A substudy and publication plan will be shared with the Steering Committee.

New substudies are welcome.

6) Next interventions

The ambition is to establish a platform trial within the SafeBoosC consortium. The aim is to introduce new interventions once successful inclusion is achieved. Please keep in mind any potential new interventions that might be of interest to test within the consortium.

7) Any other business

The next Steering Committee meeting will be in July. The date will be announced by email.