SafeBoosC-IIIv Steering Committee meeting

21 January 2026

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Adelina Pellicer (Spain), Mathias Lühr Hansen (Copenhagen Trial Unit), Livia Ognean (Romania), Paullina Toso (Chile), Lina Chalak (US), Gitte Hahn (Denmark), Saudamini Nesargi (India), Monica Fumagalli (Italy), Merih Cetinkaya (Türkiye), Eugene Dempsey (Ireland), Laishuan Wang (China), Jakub Tkaczyk (Czech Republic), Hans Fuchs (Germany),

Apologies: Renato Procianoy (Brazil), Georg Schmölzer (Canada), Tomasz Szczapa (Poland), Jorge Fabres (Chile), Cornelia Hagmann (Switzerland), Gabriel Dimitriou (Greece).

Absent: Gerhard Pichler (Austria), 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 went through the members of the Steering Committee. Gorm and Caroline have been in contact with a potential national coordinator in the UK.

3) **Central updates**
   Caroline gave an update on the central steps, including:

   a. **Randomisation**
      12 centres have started randomisation in five countries. Four additional centres are ready to randomise. 132 participants have been randomised. 61 additional centres are interested in joining the trial across 22 countries and six continents in total.

   b. **Protocol paper**
      The protocol paper is in peer review in Trials.

   c. **Statistical analysis plan**
      The statistical analysis plan was published in Trials in December 2025.

   d. **Central monitoring**
      Central monitoring of missing data has begun at Copenhagen Trial Unit. All principal investigators receive monthly reports on missing data at their site. Copenhagen Trial Unit will also send email reminders if reports of local monitoring visits are missing.

e. **Funding for step two**
Applications to cover the central costs of step two have been submitted. A €50,000 grant has been received, and further applications are in progress.

f. **Danish ethical approval**
The trial has been approved by the Danish Ethics Committee with deferred consent and is not classified as a medical device trial.

4) **National Coordinator update**
Many centres are making significant progress, which can be followed in the Trial Preparations Log (available on the website).

- **Merih, Türkiye**: Five centres are joining. A local grant application has been submitted. Working on submission for ethical approval.
- **Laishuan, China**: Ten centres are joining, with two additional centres awaiting ethical approval.
- **Gitte, Denmark**: Two centres are joining. Ethical approval has been obtained. Waiting for approval from the local department.
- **Jakub, Czech Republic**: One centre is joining. Ethical approval has been obtained. Waiting for collaboration agreement.
- **Gene, Ireland**: Two centres are joining. Funding is currently being sought. Working to avoid having the trial classified as a medical device trial.
- **Monica, Italy:** More centres will join after ethical approval is obtained. Working with the ethics committee to determine whether the trial will be classified as a device trial and whether it will be considered interventional or observational. Gorm will send a few papers on this topic.
- **Lina, US:** After initiation of the trial at one centre, additional centres will be included. Working on training of staff. Everything else is ready for randomisation.
- **Paulina, Chile:** Fourteen centres are using NIRS and could potentially join. February is a vacation period, but local progress will continue thereafter.
- **Livia, Romania:** Three new centres are potentially joining. One centre has randomised more than 30 participants. One centre is experiencing difficulties obtaining devices. Another centre has been seeking a local monitor. Livia's site is ready to begin randomisation in early February.
- **Hans, Germany**: The collaboration agreement is progressing. Ethics approval will be submitted next week.
- **Saudamini, India:** Three centres are awaiting devices, expected within the next month. Randomisation is expected to begin in two months.
- **Adelina, Spain:** One of the initial 12 centres has stepped down, leaving 11 Spanish centres. Four centres are currently randomising, while another three are ready to begin. Of the remaining centres, one is waiting for the collaboration agreement, and three are working on the delegation log and initiation visit.

5) **Substudies**
Two substudies are currently ongoing:

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

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

Saudamini is working on an additional substudy. Copenhagen Trial Unit will also present a substudy. A substudy meeting is scheduled for **15 April 2026.**

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**
   Next Steering Committee meeting will be in March. The date will be announced by email.