SafeBoosC-IIIv Steering Committee meeting

20 November 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Caroline Fray (Canada), Gabriel Dimitriou (Greece), Adelina Pellicer (Spain), Lina Chalak (US), Saudamini Nesargi (India), Jakub Tkaczyk (Czech Republic).

Apologies: Renato Procianoy (Brazil), Georg Schmölzer (Canada), Gitte Hahn (Denmark), Tomasz Szczapa (Poland), Hans Fuchs (Germany), Livia Ognean (Romania), Merih Cetinkaya (Turkey), Eugene Dempsey (Ireland), Gerhard Pichler (Austria).

Absent: Jorge Fabres (Chile), Laishuan Wang (China), Cornelia Hagmann (Switzerland), Mathias Lühr Hansen (Copenhagen Trial Unit), Gunnar Naulaers (Belgium), Gabriel Musante (Argentina), Himanshu Popat (Australia), Monica Fumagalli (Italy), 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. Massimo Di Maio (France) has stepped out of the Steering Committee since the last meeting due to lack of equipoise from the ethics committee and limited interest from the French centres. Lina and Adelina have had similar experiences with lack of equipoise in some centres in the US and Spain. Gorm has reached out to a potential national coordinator in the UK.

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

   a. **Randomisation**
      Nine centres have started randomisation in five countries. Five additional centres are ready to randomise. 97 participants have been randomised. 63 additional centres are interested in joining the trial across 22 countries and six continents in total.

   b. **Protocol paper**
      The protocol paper has been submitted to Trials and is currently assigned to editor.

   c. **Statistical analysis plan**
      The statistical analysis plan has been submitted to Trials and is currently in peer review.

   d. **Data 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**
Several applications to cover the central costs of step two have been submitted. Caroline will reach out to request information on local funding for step one from all investigators.

f. **Danish ethical approval**
A conditional approval has been received from the Danish Ethics Committee. We are still awaiting the final approval.

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

- **Adelina, Spain:** Twelve centres will participate in the trial. Four are currently randomising, and two additional centres are ready to begin. One centre in Madrid is expected to be ready to randomise in January due to the Christmas holiday period. A few centres have been difficult to reach. Caroline will contact Adelina regarding this.
- **Saudamini, India:** Nine randomisations in one centre. The other three centres are waiting for equipment.
- **Lina, US:** The Regulatory Board has approved the trial. Currently working on training of nurses. Randomisation is expected to begin before December.
- **Caroline, Canada:** Ethics committee has approved the trial. Currently working on contracts and training. Randomisation is expected to begin in January.
- **Jakub, Czech Republic:** One centre will participate. Waiting for the last formalities with contracts.
- **Gabriel, Greece:** Six centres will participate. Two centres have started randomisation. Three additional centres are working on training of the staff. The last centre is waiting for equipment.
- **Merih, Turkey**: Update on email. Plan to submit to ethics committee in the first week of December.
- **Gene, Ireland**: pdate on email: Still waiting for funding to be able to participate in the trial.

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

- **Substudy proposal on renal outcomes – Saudamini Nesargi**
14 centres are currently participating in the substudy on renal outcomes of which six centres are randomising.

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

Additional substudies are welcome. There will be a substudy meeting to discuss potential

new substudies in the beginning of the new year.

Copenhagen Trial Unit will present a substudy on environmental outcomes. Saudamini is considering a substudy on pain.

6) **Any other business**

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

Adelina raised the question of whether to ask parents for permission to continue using new data, or to use data already collected, if consent is withdrawn, as it is stated in the Standard Operating Procedure and the eCRF. It is currently built to allow parents to decline different parts of the trial. For now, this will remain unchanged, but it is ultimately up to the treating physician to decide how to handle these cases.