

SafeBoosC-IIIv Steering Committee meeting

9 July 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Saudamini Nesargi (India), Gabriel Dimitriou (Greece), Tomasz Szczapa (Poland), Gitte Hahn (Denmark), Georg Schmölzer (Canada), Gorm Greisen (Denmark), Adelina Pellicer (Spain), Lina Chalak (US).

Apologies: Hans Fuchs (Germany), Gerhard Pichler (Austria), Jorge Fabres (Chile), Jakub Tkaczyk (Czech Republic), Mathias Lühr Hansen (Copenhagen Trial Unit), Eugene Dempsey (Ireland).

Absent: Gunnar Naulaers (Belgium), Livia Ognean (Romania), Renato Procianoy (Brazil), Gabriel Musante (Argentina), Himanshu Popat (Australia), Laishuan Wang (China), Monica Fumagalli (Italy), Cornelia Hagmann (Switzerland), Merih Cetinkaya (Turkey), 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. There have been no changes to the Steering Committee since the last meeting.

3) Central updates

Caroline gave an update on the central steps, including:

a. Randomisation

Currently, four centres have started randomisation. Four additional centres are ready to randomise. 32 participants have been randomised.

b. Emergency randomisations

If anyone experiences issues with the randomisations, please call Caroline at +45 29 32 41 08 (day and night), and she will fix the problems or perform an emergency randomisation.

c. Protocol paper

The protocol paper has been sent to the Steering Committee. The deadline for comments is 12 July 2025. All authors of the protocol paper will receive the draft after the holidays.

d. Change of Danish ethical approval

Caroline has sent out a letter from the Danish Research Ethics Committee stating that the trial is not considered a device trial in Denmark. It will take a few months before we receive the new approval from the Danish ethics committee.

e. Step two

Based on the last Steering Committee meeting, it seems feasible to conduct step two with only central funding. CTU is currently applying for funding to cover the central costs of step two and offers to organise it under the same set-up as step one.

4) National Coordinator update

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

- **Adelina, Spain:** Three centres are currently randomising. Some centres are still working on the contracts. Many centres are positive about participating in step two.
- **Saudamini, India:** Goa is waiting for equipment before randomisation can begin. One centre has just received ethical approval and is now proceeding with contracts. Another centre is awaiting ethical approval, and the last centre is waiting for insurance.
- **Gabriel, Greece:** One centre is ready to randomise. Two centres have received sensors, but other centres are experiencing equipment delays at customs.
- **Tomasz, Poland:** Ethics approval obtained. More than eight centres are interested in joining the trial. Focusing on the contracts and receiving equipment.
- **Lina, US:** Ethics approval obtained. Currently completing training. Lina has reached out to a centre in Canada.
- **Georg, Canada:** Currently applying for funding, obtaining ethics approval, working on contracts, and reaching out to additional centres.
- **Gitte, Denmark:** Waiting for ethical approval. Two centres will join. Rigshospitalet has received sensors.
- **Hans, Germany:** Update on email. Working on contracts.
- **Jakub, Czech Republic:** Update on email. Waiting for ethics committee approval and contracts and expecting randomisation to start in the autumn.

5) Substudies

Two substudies are currently ongoing:

- **Substudy proposal on renal outcomes – Saudamini Nesargi**
11 centres are currently joining the substudy on renal outcomes. An updated protocol will be circulated with the minutes.
- **Substudy proposal on hypocapnia – María Carmen Bravo**
Six centres are currently participating in the substudy on hypocapnia. An updated protocol has been circulated recently.

Additional substudies are welcome.

6) Any other business

Next Steering Committee meeting will be 17 September at 16:30-17:30 CEST.