

SafeBoosC-IIIv Steering Committee meeting

17 September 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Jorge Fabres (Chile), Laishuan Wang (China), Saudamini Nesargi (India), Georg Schmölzer (Canada), Hans Fuchs (Germany), Gabriel Dimitriou (Greece), Jakub Tkaczyk (Czech Republic), Gitte Hahn (Denmark), Renato Procianoy (Brazil).

Apologies: Adelina Pellicer (Spain), Cornelia Hagmann (Switzerland), Livia Ognean (Romania), Tomasz Szczapa (Poland), Mathias Lühr Hansen (Copenhagen Trial Unit), Eugene Dempsey (Ireland).

Absent: Lina Chalak (US), Gerhard Pichler (Austria), Gunnar Naulaers (Belgium), Gabriel Musante (Argentina), Himanshu Popat (Australia), Monica Fumagalli (Italy), 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

Seven centres have started randomisation. Five additional centres are ready to randomise. 54 participants have been randomised.

b. Protocol paper

The protocol paper has been submitted to Trials.

c. Statistical analysis plan

The statistical analysis plan has been sent to the Steering Committee, with a deadline for comments on 23 September 2025. We plan to apply the same authorship criteria as those used for the protocol. All authors of the statistical analysis plan will receive the draft at the end of September.

Gorm mentioned that publications in Trials might be delayed. We will be prepared to follow up with the journal if necessary.

d. Central monitoring

Central monitoring of missing data will begin at Copenhagen Trial Unit. All principal investigators will receive monthly reports on missing data.

e. jENS Investigator Meeting

Caroline and Johanne have scheduled an investigator meeting at jENS in Belgrade, Serbia, on 24 October from 8:30 to 10:30. Investigators are kindly requested to confirm their attendance. For those unable to join the investigator meeting, it will be possible to arrange an individual meeting Thursday or Friday.

4) National Coordinator update

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

- **George, Canada:** The protocol has been submitted to the ethics committee. Work is ongoing on contracts and funding. Randomisation is expected to begin in a few months.
- **Gabriel, Greece:** Five centres will join. Paperwork is in progress, while some centres are waiting for sensors. Randomisation is expected to begin in October at the last centres.
- **Laishuan, China:** Work on contracts is ongoing. Randomisation is expected to begin in October. Laishuan will send a list of the other Chinese centres to Caroline.
- **Saudamini, India:** The first participant was randomised yesterday. The other three centres are working on obtaining sensors, contracts, and ethical approval.
- **Hans, Germany:** The centre in Freiburg will be the only centre in Germany. Work on the contract is ongoing.
- **Jakub, Czech Republic:** One centre will join. Waiting for the last formalities. The lack of funding may be a barrier for other centres to join.
- **Renato, Brazil:** The protocol has been approved by the ethics committee, although some centres may need small adjustments. Work is ongoing on the last contracts and obtaining sensors.
- **Gitte, Denmark:** Two centres are joining. Waiting for ethical approval.
- **Jorge, Chile:** No update.
- **Adelina, Spain:** Update provided by email. Four centres are randomising, and one additional centre is ready to randomise. Adelina will reach out to all principal investigators to follow up on their progress.
- **Tomasz, Poland:** Update provided by email. One more centre has received ethical approval. OxyPrem will support the Polish centres with first-generation sensors.

5) Substudies

Two substudies are currently ongoing:

- **Substudy proposal on renal outcomes – Saudamini Nesargi**
11 centres are currently participating in the substudy on renal outcomes.
- **Substudy proposal on hypocapnia – María Carmen Bravo**
Six centres are currently participating in the substudy on hypocapnia.

Additional substudies are welcome. There will be a substudy meeting to discuss potential new substudies at the end of the year.

6) Any other business

Next Steering Committee meeting will be in November. The date will be announced on email.