

SafeBoosC-IIIv Steering Committee meeting

25 March 2026

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Gabriel Dimitriou (Greece), Adelina Pellicer (Spain), Renato Procianoy (Brazil), Jakub Tkaczyk (Czech Republic), Gabriela Trindade (Brazil), Merih Cetinkaya (Türkiye), Tomasz Szczapa (Poland), Paullina Toso (Chile), Georg Schmölzer (Canada), Gitte Hahn (Denmark).

Apologies: Hans Fuchs (Germany), Saudamini Nesargi (India), Livia Ognean (Romania).

Absent: Mathias Lühr Hansen (Copenhagen Trial Unit), Lina Chalak (US), Monica Fumagalli (Italy), Eugene Dempsey (Ireland), Laishuan Wang (China), Jorge Fabres (Chile), Cornelia Hagmann (Switzerland), 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. Caroline has been in contact with a potential national coordinator in the UK, although it has not yet been possible to confirm anyone for the role.

3) Central updates

Caroline gave an update on the central steps, including:

a. Randomisation

16 centres have started randomisation in five countries. One additional centre is ready to randomise. 189 participants have been randomised. 53 additional centres are interested in joining the trial across 22 countries and six continents in total. Currently, the predicted time until randomisation is completed is 2.3 years.

b. Protocol paper

The protocol paper has been published in Trials. The published protocol will be shared with the March newsletter.

4) National Coordinator update

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

- **Gabriel, Greece:** Five centres are randomising. One centre has issues with the ethics committee but is in contact with Gabriel to resolve this.

- **Adelina, Spain:** Almost all 11 centres are ready to randomise. Eight centres have started randomisation or are ready to begin. One centre has had issues with the local monitor, another with the contract, and the final centre is scheduled for a meeting with Adelina to follow up.
- **Paulina, Chile:** Due to the summer vacation, February and March have been slow. Ten centres are interested in joining the trial. It is currently expected that the application for ethics approval will be submitted in April.
- **Renato, Brazil:** Eight centres are interested in joining the trial. Some centres have received ethics approval, while others have not yet applied. One centre is awaiting devices and will start randomisation afterwards.
- **Gitte, Denmark:** Currently applying for funding. The local hospital has approved the study to begin in 2027.
- **Georg, Canada:** Currently waiting for signing the contract. Ethics approval has been obtained. Once the contract is signed, the remaining steps can be completed.
- **Merih, Türkiye:** Five centres are interested in joining. Approval from the local ethics committee has been obtained, but approval from a national committee is still needed. An application for funding was submitted in February.
- **Tomasz, Poland:** Eight centres are interested in joining the trial. Three centres are expected to begin randomisation in April. One centre has issues with ethics approval but is in contact with Tomasz to resolve this.
- **Jakub, Czech Republic:** Ethics approval has been obtained. Currently waiting for the collaboration agreement.
- **Saudamini, India:** Update via email. One centre has started randomisations. Three centres have received devices and are expected to start randomising soon.

5) Substudies

Two substudies are currently ongoing:

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

A new substudy was proposed:

- **Substudy on cardiovascular support – Kosmas Sarafidis**
Kosmas Sarafidis has proposed an ancillary study on NIRS Monitoring and Cardiovascular Support in Neonates. Members of the Steering Committee suggested making the substudy simpler and more pragmatic, with fewer data points or a defined timeline, similar to the hypocapnia substudy. The substudy was approved by the Steering Committee and will be presented and further discussed at the substudy meeting in April. If anyone not present at the meeting has any comments for the substudy, please write an email to Caroline or Johanne.

New substudies are welcome. 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 May. The date will be announced by email.