

SafeBoosC-IIIv Steering Committee meeting

21st May 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Janus Christian Jakobsen (Copenhagen Trial Unit), Gorm Greisen (Denmark), Gunnar Naulaers (Belgium), Gerhard Pichler (Austria), Jakub Tkaczyk (Czech Republic), Saudamini Nesargi (India), Adelina Pellicer (Spain), Eugene Dempsey (Ireland), Lina Chalak (US), Gabriel Dimitriou (Greece).

Apologies: Livia Ognean (Romania), Mathias Lühr Hansen (Copenhagen Trial Unit), Gitte Hahn (Denmark), Renato Procianoy (Brazil).

Absent: Gabriel Musante (Argentina), Himanshu Popat (Australia), Jorge Fabres (Chile), Laishuan Wang (China), Hans Fuchs (Germany), Monica Fumagalli (Italy), Tomasz Szczapa (Poland), 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

Since the last Steering Committee meeting, we have been in contact with Georg Schmölzer from Canada, Massimo Di Maio from France, and Charles Roehr from the United Kingdom on the possibility of joining the trial. Siv Fredly from Norway, Thalia Papadouri from Cyprus, and Daniel Virella from Portugal have withdrawn from the trial. Centres are still being recruited.

3) Central updates

Caroline gave an update on the central steps including:

a. Randomisation

Currently, four centres have started randomisation. 18 participants have been randomised.

b. FAQ

The trial is conducted according to the intention-to-treat principle. If an infant appears to meet the eligibility criteria at the time of randomisation, and a brain injury or another exclusion criterion is diagnosed later, everything should proceed as planned. This includes collecting follow-up data, and the participant should not be excluded from the trial.

c. 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.

d. Protocol paper

The Copenhagen Trial Unit will work on the protocol paper in the following month.

e. Change of Danish ethical approval

Caroline sent an email regarding the possibility of changing the Danish ethical approval. All responses have been positive. Copenhagen Trial Unit will proceed with the change and prioritise a prompt update of the protocol to ensure it is readily available for all countries.

4) National Coordinator update

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

- **Gunnar, Belgium:** Waiting for ethical approval. Funding from SafeBoosC-III will be used.
- **Gerhard, Austria:** One centre has obtained ethical approval, while another centre is still awaiting approval. The contract is currently being finalised.
- **Gene, Ireland:** Interest from two centres. Waiting for the new protocol to submit to the ethical committee.
- **Saudamini, India:** One centre has obtained ethical approval and finalised contracts but is waiting for equipment. The remaining centres are awaiting ethical approval and resolution of insurance issues.
- **Adelina, Spain:** Three centres are randomising. A few centres are still working on the contracts.
- **Lina, US:** Recruiting centres. Some sites do not have equipoise and will therefore not participate in the trial.
- **Jakub, Czech Republic:** Waiting for the new protocol to submit to the ethical committee. In contact with OxyPrem.
- **Gabriel, Greece:** One site has received equipment. The remaining centres are experiencing issues with taxes. Everything else is ready for randomisation.

Caroline also went through the primary outcomes for step two of the trial and asked the national coordinators whether step two with 3000 participants would be realistic without additional funding. Everyone was positive on the continuation of the trial for step two. Copenhagen Trial Unit will apply for funding to cover the central costs of step two.

5) Substudies

Two substudies are currently ongoing:

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

6) Any other business

Next Steering Committee meeting will be announced on e-mail.