

SafeBoosC-IIIv jENS Investigator Meeting

24 October 2025

Present: Caroline Kamp (Copenhagen Trial Unit), Johanne Juul Petersen (Copenhagen Trial Unit), Ruth del Rio Florentino (Spain), Miguel Alsina-Casanova (Spain), Marie Isabel Skov Rasmussen (Denmark), Hans Fuchs (Germany), Kosmas Sarafidis (Greece), Christina Thomou (Greece), Eleftheria Hatzidaki (Greece), Evangelia Papathoma (Greece), Gabriel Dimitriou (Greece), Livia Ognean (Romania), Adelina Pellicer (Spain), Nariae Baik-Schneditz (Austria), Gerhard Pichler (Austria), Renato Procianoy (Brazil), Rita Silveira (Brazil) and Merih Cetinkaya (Turkey).

1) Approval of the agenda

Agenda approved.

2) Organisation

Caroline went through the SafeBoosC-IIIv organisation and members of the Steering Committee.

3) Central updates

Caroline and Johanne gave an update on the central steps, including:

a. Randomisation

Five countries and eight centres have started randomisation. Five additional centres are ready to randomise. 74 participants have been randomised.

b. Protocol paper

The protocol paper has been submitted to Trials.

c. Statistical analysis plan

The statistical analysis plan will be submitted to Trials next week.

d. Funding for step two

Copenhagen Trial Unit has submitted a large application for funding for SafeBoosC-IIIv step two.

e. Central monitoring

Central monitoring of missing data has begun at the Copenhagen Trial Unit. All principal investigators will receive monthly reports on missing data. The Copenhagen Trial Unit will also remind investigators about local monitoring visits if the reports are not received every three months.

4) Substudies

Two substudies are currently ongoing:

• Substudy proposal on renal outcomes – Saudamini Nesargi

14 centres are currently participating in the substudy on renal outcomes.

- **Substudy proposal on hypocapnia – María Carmen Bravo**
10 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.

5) Investigator update

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

- **Ruth:** Working on the contract.
- **Miguel:** Randomisation has started, but there are only a few eligible infants.
- **Marie:** Denmark is waiting for the ethical approval.
- **Hans:** Working on the contract.
- **Kosmas:** Randomisation has started, but there are only a few eligible infants. Might be interested in participating in the substudies and initiating a new substudy.
- **Christina and Eleftheria:** Ready for randomisation.
- **Lilly:** Ready for randomisation next week after the local monitor initiation visit.
- **Gabriel:** Ready for randomisation.
- **Livia:** One centre cannot get the equipment, but a new centre may join the trial. Other centres are ready for randomisation soon.
- **Adelina:** Randomisation has started, and the first local monitor visit was last week.
- **Nariae:** Ready for randomisation. Will try to obtain deferred consent once the trial is running.
- **Gerhard:** One more centre is working to get started. Currently working on increasing staff commitment.
- **Renato and Rita:** Five or six centres will join. Some centres are waiting for ethical approval and equipment. Randomisation is expected to start in February after summer vacation.
- **Merih Cetinkaya (update before the meeting):** Five centres will join. Currently applying for funding.

6) Any other business

Next Steering Committee meeting will be on 20 November 2025.