

SafeBoosC-IIIv substudy meeting

5th February 2025

Present: Caroline Kamp, Johanne Juul Petersen, Janus Christian Jakobsen, Gorm Greisen, Elke Griesmaier, Manuela Lopez Azorin, Kosmas Sarafidis, Ramona Mohora, Ida Tjell, Miguel Alsina, Paula Costa, Adelina Pellicer, Livia Ognean, Gabriel Dimitriou, Maria Carmen Bravo, Hatzidaki Eleftheria, Laura Serrano Lopez, Eleni Agakidou, Manuela, Izaskun, Saudamini Nesargi, Lina Chalak, Raquel González, Dimitrios Rallis

Apologies: Fernando Cabañas, Gunnar Naulaers, Salvador Piris, Jakob Tkaczyk, Mathias Lühr Hansen,

Moderator: Caroline Kamp

Minute taker: Johanne Juul Petersen

1) Presentation of standard operating procedure

Caroline presented the [standard operating procedure](#) on substudies. Investigators are allowed to plan and conduct substudies. All substudies need approval by the Steering Committee. Proposals must be sent to caroline.kamp@ctu.dk. A list of eCRF data points will be available on the website soon. All investigators will be informed in due course. Current substudy proposals will be discussed at the next Steering Committee meeting on the 19th of March 2025, 20:30 CET. An additional substudy meeting will be scheduled for a later date.

2) SafeBoosC-III magnetic resonance imaging (MRI) substudy

Miguel Alsina presented a substudy from SafeBoosC-III as inspiration for SafeBoosC-IIIv investigators. The substudy assessed whether cerebral oximetry decreased the global brain injury score on MRI at 36–44 weeks of postmenstrual age. Eight centres from five countries participated in the substudy. The substudy concluded that cerebral oximetry did not lead to significant alterations in brain injury as determined by MRI.

3) Substudy proposal on hypocapnia

María Carmen Bravo presented a substudy on cerebral oximetry for preventing hypocapnia in newborns, with the hypothesis that cerebral oximetry will decrease the number of episodes of hypocapnia. María outlined the primary outcome, inclusion and exclusion criteria, and methods. A sample size of 56 newborns was calculated based on prior data. The potential substudy was discussed among the participants of the meeting.

4) Substudy proposal on renal outcomes

Saudamini Nesargi presented a substudy on the effects of treatment guided by cerebral oximetry on renal outcomes, with the hypothesis that cerebral oximetry will decrease the incidence of death, acute kidney injury, and renal replacement up until discharge. Saudamini outlined the primary outcome, inclusion and exclusion criteria, and methods. A sample size of 850 newborns was calculated based on previously published data. The potential substudy was discussed among the participants of the meeting.

Please contact caroline.kamp@ctu.dk if you are considering conducting a substudy, so we can support you in the process of planning the study.