

SOP: completion of SafeBoosC-III and submission of manuscript

Version	Author(s)	Date	Changes	Approved by
1.0	Marie Isabel S Rasmussen, Gorm Greisen	22.04.24	Initial version	Steering Committee

Rationale

In the SafeBoosC-III trial, treatment guided by cerebral oximetry monitoring for the first 72 hours after birth did not reduce the incidence of death or severe brain injury in extremely preterm infants at 36 weeks' postmenstrual age, as compared with usual care. Of the 1601 infants randomised in the SafeBoosC-III trial, 1276 infants were alive at 36 weeks' postmenstrual age and will potentially be available for the two-year follow up. The first infant turned two years of corrected age in September 2021 and the last infant will turn two years of corrected age in April 2024. To enhance the quality of the study results, it is important that all possible data entries are completed, that random and systematic errors identified during central data monitoring are handled. Until this work is done, statistical analyses cannot be initiated, and the results cannot be made available to the public. To enhance the process of completing the trial and submitting the manuscript for publication without compromising the quality, we have developed this standard operation procedure. The aim is to create a simple overview of expected important deadlines and tasks for investigators, so that they can make the necessary preparations in time.

Expected timeline for completion of SafeBoosC-III and submission of manuscript.

19th of April 2024 – last participant reaches two years of corrected age

8th of August 2024 – First round of central data quality monitoring

19th of October 2024 – last participant reached 30 months of corrected age and deadline for completion of data entries

20th of October 2024 – second and last round of central data quality monitoring

20th of November 2024 – 1) deadline for inquiries arisen from the data quality monitoring

2) initiation of statistical analysis

18th of December 2024 – 1) completion of statistical analysis

2) two blinded abstracts are written

3) investigator meeting through Zoom: presentation, discussion and unblinding of abstracts

10th of January 2025 – manuscript circulated in investigator group

24th of January 2025 – deadline for comments and suggestions to manuscript

31th of January 2025 - submission to peer reviewed journal