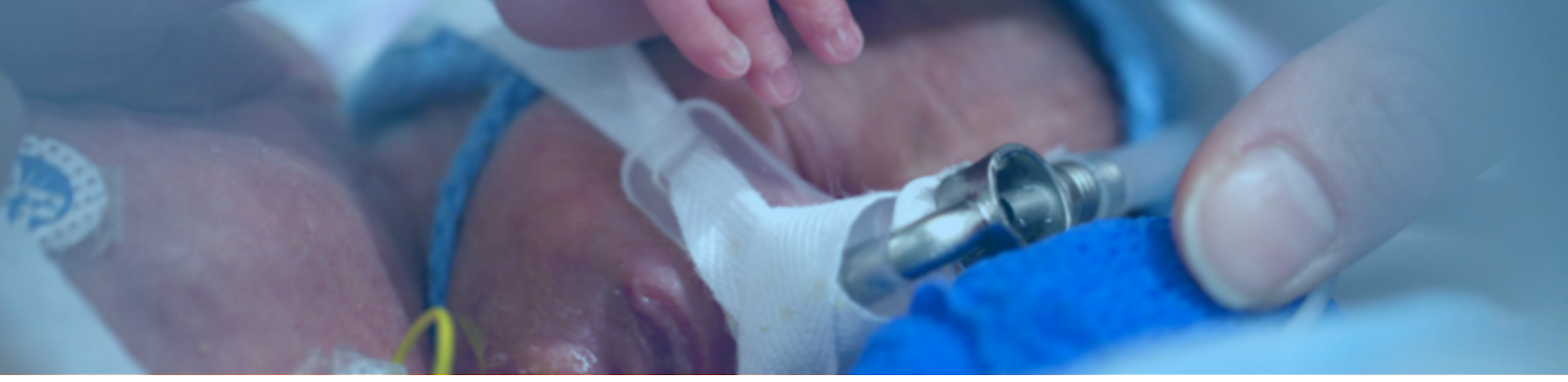

SafeBoosC News

NEWSLETTER APRIL 2019

SafeBoosC-III

Dear investigators

Welcome to the April version of SafeBoosC newsletters. Since we approach the randomization of the first baby, this letter contains important information. Please, read carefully.

More than a year ago, we planned that we would start randomising babies in April, and we are in a situation were some departments are indeed ready to randomise. However, we still have some issues to solve here in Copenhagen.

Trial preparations in Copenhagen
Collaboration agreements
Finalising the collaboration agreement is complicated due to the GDPR (EU General Data Protection Regulation). Our data protection office struggles to do it correctly and yet in a practical way. We think that we are almost there, and plan to send it first to those of you who informed us that you are ready to receive it and have it signed by your hospital.

Web-based training and certification program
During the last months we have piloted the training module on NIRS monitoring. It was well received, but the responses showed room for improvements. These have now been implemented. We are programming the last training modules and will reach out to you as soon as the training package is ready.

Case report form
Copenhagen Trial Unit is programming and pilot-testing the electronic case report form and the randomisation mechanism. Both will run by password protected, end-to-end encrypted web-access. It will be ready before the end of April.

New Standard Operating Procedure
We have developed a new standard operation procedure on diagnosing and classification of of severe brain injury that match the training program.

https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sops/sop-diagnosis-and-classification-of-brain-injury.pdf

Trial preparation in local departments
Some of you have obtained ethics approval and some have reported the number of staff members on the training and delegation log.

We want to keep track of how far all of us are in the preparation process. Therefore, a SafeBoosC preparation log is found on www.safeboosc.eu. It is meant as an overview.

https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/safeboosc-iii-preparation-log-290319.pdf

Please continue preparations locally as fast as you can, as described in the SOP: tasks for principal investigators and provide us with the necessary information on a continuous basis, and we will update the preparation log without delay.

When will the first baby be randomized?
We are unsure if randomisation can start during April, but we are quite confident that the first baby will be randomized in May. We are curious to see by whom!

Minor protocol amendments
Based on recommendations from Copenhagen Trial Unit, we have decided to include 'gender' as an explanatory variable in the protocol, since it will serve as a control measure of successful randomisation. Therefore, a protocol version 1.2.2 including this, and some other minor amendments, have been uploaded to www.safeboosc.eu.

Direct link:
https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Sider/the-protocol.aspx

Hypoxic thresholds for oximeters
All cerebral oximeters that are approved for clinical use in newborns may be used in SafeBoosC III. There are now six commercially available devices, and we expect number seven (Oxyprem) to be be CE-marked in April.

The hypoxic intervention threshold for each device and sensor combination, can be found in the SOP 'Hypoxic threshold for cerebral oximeters' which will be continuously updated as we finish the calibration.

https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sop-hypoxic-threshold-oximeters-010419.pdf

Organizational changes
Due to other academic commitments, Topun Austin has resigned as national coordinator in the UK (England). We grateful to Topun for the effort he has put into the SafeBoosC project. As for now, we are unsure who will take over the role as coordinator in England.

The Netherlands has withdrawn from the trial due to a competing randomised clinical trial, the BeneDuctus trial which involve almost all Dutch NICUs. The Beneductus steering committee decided that their trial was not compatible with SafeboosC. Fortunately we only lost the support of two NICUs due to this.

Statistical analysis plan version 1.0 written
The statistical analysis plan has been finalised and a manuscript is drafted for publication. For now, it is under revision by the steering committee. We expect both the design- and statistical analysis papers to be published prior to any data analysis.

Data Safety and Management Committee
Professors Andrew Whitelaw, Oslo, James Boardman, Edinburgh, and Theis Lange, Copenhagen (statistician) have approved to serve as the DMSC.

Thank you for your time,
Gorm and Mathias

REGION H Rigshospitalet