



SafeBoosC III
SAFEGUARDING THE BRAIN OF OUR SMALLEST CHILDREN

Newsletter June 2019

Dear investigators

Welcome to the June version of the SafeBoosC III newsletter. Since we have started randomising babies, this newsletter contains a lot of information.

Opened for randomisation

We have enrolled the first two babies at Rigshospitalet in Denmark. We hope that you soon can start randomising babies as well. Let us know if we can do something to help you in this.

Collaboration agreement finalised

The collaboration agreement has been finalised and was sent out last week, including an appendix on data processing instructions and an EU data management contract for countries outside EU. Once again, we apologise for this delay. We hope that the process of getting the agreement signed, will not cause you too much trouble.

Ethics approvals

For now, 14 departments have informed us that they have received REB/IRB approval, including Sponsor site (Rigshospitalet, Denmark). If you wish to follow the preparation process of other SafeBoosC III departments, please look at the SafeBoosC III preparation log, which will be updated continuously, as principal investigators update us on their progress:

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

Also, please inform us on your own trial preparations on a continuous basis.

Web-based training and certification has opened

The online training program for SafeBoosC III is open. The use is voluntary, but we hope that as many as possible of you and your colleagues, will use it, for the benefit of the SafeBoosC-III trial as well for professional competence and patient care. The information on how to log-in, including enrolment key, will be mailed to you as soon as we have received the number of clinicians on the delegation and training log. We

will keep you updated on how many from your hospital that has been certified, and the total statistics will be part of the final publication of the trial.

Direct link: www.trialeducation.info

Attachment to parental information on European General Data Protection Regulation (GDPR)

The appendix regarding European data regulation as well as subject rights has now been uploaded (see bottom of page):

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Sider/parental-information-and-consent-form.aspx>

In order to adhere to these regulations (GDPR), the appendix must be attached to the parental information sheets. The argument for doing this, is to ensure that parents are aware of how their baby's data will be processed, as well as their rights.

SafeBoosC III meeting at jENS in September, Maastricht

There will be a SafeBoosC III consortium meeting at jENS conference in Maastricht, in September. The meeting is open for SafeBoosC investigators as well as other interested colleagues. An agenda will be sent out in August. If you have any topics that you want to discuss at the meeting, please let us know. We hope to see as many of you (and your interested colleagues) as possible.

Steering group meeting

The second SafeBoosC III steering group e-meeting was held in May,. A summary of the meeting can be found at the website under "Newsletters and steering group meetings".

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Sider/newsletters.aspx>

Hypoxic threshold for new devices

The hypoxic threshold has been determined for EnginMed neonatal sensor (56%), Oxyprem 1.4 (48%) and Masimo neonatal and pediatric sensor (64% and 64%). As previously, all new hypoxic thresholds have been, and will be, added to the SOP: hypoxic thresholds for cerebral oximeters:

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

Thank you for your time,
Gorm and Mathias