

Dear investigators

Welcome to the first SafeBoosC newsletter. We plan to circulate a newsletter regularly and publish it on the website as we did in the SafeBoosC-II project.

Funding status

Medtronics decided not to support the trial. However, Oxyprem will be CE-marked latest May, and will be able to provide 100 free-to-loan oximeters (their sensor is reusable) and will also offer a money-for-data agreement. Most national coordinators, have already been contacted by Alexander from Oxyprem. If you have not heard from him, and are interested in the Oxyprem offer, please contact him at +41 76 263 87 31 or nitsch@oxyprem.com.

Furthermore, we have had a meeting with the Nonin Company, who is also interested in supporting the trial. They will develop a 'package offer' to participating NICUs, within the near future. If you wish to hear more, or contact Nonin directly, please contact Jamie Hoffman, at jamie.hoffman@nonin.com, and Jill Wroblewski, at jill.wroblewski@nonin.com.

We still hope that all of you who need extra funding, will continue to apply for this.

Contract between Copenhagen and participating NICUs

A bilateral contract between Copenhagen and each participating NICUs is underway. The contract will be simple, and only include agreements on data sharing and publications. Since some of you need it for ethics application, we work fast.

First ethical approval

Ebru Ergenekon (national coordinator) have ethics approval of the SafeBoosC protocol in Turkey, covering all five participating Turkish NICUs. Ebru have decided to apply for and use standard prior informed consent.

The ethics application in Denmark was filed some weeks ago after a consensus process with the 4 Danish Principal Investigators, as we have a network of regional ethics committees where the national coordinator applies for all NICUs. We decided to apply for deferred consent. If this is not accepted, we will go for standard prior consent, as 'opt-out' is not a possibility in Denmark. This will not delay the decision which has to be made within 60 days from first filing.

Web-based training and certification program

We are pilot-testing the web-based training and certification program module on NIRS-monitoring. We started in China and Denmark and next week, we expect piloting to start in Spain as well..

Calibration of EnginMed NIRS device, Egos

All oximeters used in SafeBoosC must have defined the appropriate hypoxic intervention threshold corresponding to a $rStO_2$ value of 55%, using the INVOS adult SomaSensor. The value will be determined by a blood lipid phantom experiment. The hypoxic threshold has been determined for most oximeters on the market. As in last week, the Chinese oximeter, Egos, from EnginMed, also underwent the phantom test.

Thank you for your time,

Best wishes

Gorm and Mathias