Minutes from SafeBoosC III Steering Committee Meeting – 26th of May 2021

Attendees: Gunnar Naulaers, Jonathan Mintzer, Janus Christian Jakobsen, Tomasz Szczapa, Jakub Tkaczyk, Eugene Dempsey, Christian Gluud, Anne Marie Heuchan, Maria Vestager, Mathias Lühr Hansen, Gorm Greisen, Marie Rasmussen, Gabriel Dimitriou, Saudamini Nesargi, Siv Fredly, Simon Hyttel-Sørensen, Monica Fumagalli

Apologies: Anne Marie Heuchan, Adelina Pellicer, Hans Fuchs, Gerhard Pichler, Ebru Ergenekon,

Absent: Guoquiang Cheng, Ana Vilan, Cornelia Hagmann

Trial status update from Copenhagen - Mathias

Overall, the trial is progressing well. Currently, 71 sites are open for randomisation. Nine additional sites are still preparing to participate. As of the 26th of May 2021, 1072 participants have been randomised. The average performance per centre is below the prespecified goal. However, more sites than first estimated have joined the trial, so the current randomisation rate is 2,4 patients per day. If the current randomisation rate persists, we will reach our sample size of 1600 patients before the end of 2021.

It was discussed whether some sites, that have been randomising for a long time simply have gotten tired and thereby recruit less. This does not seem to be the case. It was discussed how it may be possible to raise awareness of the trial in the respective sites, so that more eligible babies are recruited. The web-based training program has a 80% certification rate of those who created a user. It was proposed to study the treatment effect vs the web-based training certifications, when we have the final data.

The SafeboosC-IIIfu study and a discussion on the protocol - Marie

As discussed previously, the SafeBoosC-IIIfu will rely on routine clinical data as well as parental questionnaires. So far, 38 departments have declared interest in participating. We did not get funding from Elsass (cerebral palsy foundation) but have applied for a grant from the Innovation Foundation, which we will receive a preliminary answer from this summer. The first babies will reach two years of corrected age this fall. Marie will be working full time on the study this fall, to ensure that sites get a good start with the follow up study. Furthermore, we have had a meeting with Samantha Johnson and Dieter Wolke, who are the experts behind the PARCA-R questionnaire, who are keen to help us with developing a pragmatic solution for the parental questionnaires.
A discussion regarding the protocol revealed a need for the exploratory outcomes to be condensed. Once revised, the protocol will be circulated in the Steering Committee again for approval, before it is sent to the principal investigator and the ethics committees.

Co-authorships - Gorm
Gorm invites the steering committee to discuss the non-byline authorships, which have been used for principal investigators in the central monitoring manuscript, and which we intend to offer to the blinded 2-year outcome assessor in the SafeBoosC-IIIfu. The PI would be given a regular co-authorship and the blinded assessor would be given a non-byline authorship. This means that their name would not appear in the byline but would be stated in an appendix and appear in a PubMed search. Several members believe that credit may also seem fit for the blinded cUS assessor in the SafeBoosC-III trial.

For more information on authorships please see the following manuscript from JAMA:
https://jamanetwork.com/journals/jama/fullarticle/2667044

For information regarding the MedLine search please see the following webpage:
https://www.nlm.nih.gov/bsd/policy/authorship.html

Closing the door for new sites randomising 3.0

It is decided that sites already preparing may continue to do so, until the trial reaches the full sample size of 1600 patients. However, if no participants have been recruited from a site, and they thereby have not contributed with data to the final analysis, they will not be offered co-authorship on the final manuscript. It is acknowledged that several sites have had major delays due to ethics committees, lawyers etc. Members from the Steering Committee proposed that a retrospective study describing the obstacles, which participating sites have met when preparing for the trial, would be valuable.

Update on the SafeBoosC-IIIv trial
The preparations for the trial are progressing. Funding applications have been sent to the Innovation Foundation with preliminary result in July. We will also apply for the Novo Nordisk Foundation, which has a deadline in August, and results in December. An abstract for the jENS congress has furthermore been submitted, based on the protocol, which we expect to have a first draft ready during the Summer.

Investigator meeting 2022?
If the pandemic allows it, we will hopefully plan an investigator meeting in the beginning of 2022. Tomasz suggest a hybrid meeting where it is possible to attend both physically and virtually.

No further business