Minutes from the SafeBoosC Steering Committee Meeting the 30th of November 2022

Present: Tomasz Szczapa, Jakub Tcakzub, Janus Jakobsen, Simon Hyttel-Sørensen, Eugene Dempsey, Saudamini Nesargi, Gunnar Naulaers, Hans Fuchs, Marie Rasmussen, Maria Vestager, Mathias Lühr Hansen, Gorm Greisen

Apologies: , Jonathan Mintzer, Ebru Ergenekon, Adelina Pellicer, Gerhard Pichler, Christian Gluud, Siv Fredly. Monica Fumagalli and Gabriel Dimitriou sent apologies later that evening, had been taken by clinical duties.

Absent: Guoqiang Cheng, Cornelia Hagmann, Anne Marie Heuchan

Topics from the SafeBoosC-III FU study

Status

The study has been going for a little more than a year. No sites have officially declined to participate yet. So far, 28 of 40 sites with eligible children are open for follow-up and 25 have entered data in OpenClinica. Seven sites are actively preparing while the status of two sites are unknown. We aim at minimizing the number of children without follow-up, meaning that if there is no routine follow-up program for extremely preterm infants in a specific site, the site should focus on the parental questionnaires. To date, a total of 324 children are more than two years of corrected age. Of these, 199 have completed data entries in OpenClinica (of which 12 of 199 are reported 'lost to follow-up', 115/199 have completed the Bayley scores) and 165/199 have completed the parental questionnaires. Nine infants are now older than 30 months of corrected age but with no data entries yet. Gene raised a concern regarding lost to follow-up saying that we actually only have 115 of 324 potential Bayley scores which is lower than 58% (115/199). The remaining participants, who are older than 24 months of corrected age and less than 30 months of corrected age, but have not had data entries in OpenClinica yet, are not accounted for as missing. These data entries are waiting to be filled out. Therefore the number of Bayleys may be lower than 58%, however, not as low as it may seem. Marie explained that monthly reminders are sent out to individual investigators regarding incomplete data, but would like to discuss other ideas on how to encourage follow-up. It is a challenge that we do not know what is due to clinical follow-up not being done and what is due to delay in PIs and blinded assessors report in OpenClinica. We cannot push for more clinical assessments than the ones actually done routinely.

Challenges and how to overcome them

The participation rate for the parental questionnaires is only 56% – how can we increase this? Gunnars team usually sends direct e-mails to the parents prior to the follow-up consultation. The parents can often fill-out parental questionnaires online. In cases where parents cannot fill-out the questionnaires online (low socio-economic groups), they try to do the parental questionnaires in the follow-up clinic together with the parents. In India (Saudamini's team) they contact the parents by phone prior to sending the questionnaire in order to motivate them, and sometimes do the questionnaire as a telephone interview. It may be an idea to give parents immediate feedback on the questionnaire. If helping the parents fill out the questionnaire, investigators could either use the PARCA-R manual for instant scoring and feedback or give feedback to parents on specific questions such as "how nice that your child can stack three bricks on top of eachother".

When is a site not eligible to participate anymore?

Two sites in Spain has passed six months since the first child reached 24 months of corrected age. The sites have shown interest but not made any progress on the preparations. Janus said that there is a methodological reason as to be strict regarding the initiation of site since sites not participating in the follow-up study at all will not count as missing data per se. Since we were not a quorum at the SC meeting we will have to do this vote by e-mail.- two options: either fighting for some follow-up data for every randomised infants or to exclude sites up-front where data will end up being missing for many or even all infants..

Marie also gave a short status on the CogniTOT study. 11 sites will participate, and it has been initiated in Copenhagen. Sites are still welcome to participate.

SafeBoosC-IIIv study protocol

Authorships - Proposal: Members of steering group who decide to participate in SFB-IIIv

No other proposals or arguments against it. An e-mail regarding voting will be sent out.

Inclusion criteria: GA<28 weeks PMA – should we include these?

Pros: more patients to include and simpler inclusion criteria

Cons: even more patient heterogeneity, patient group of SFB-III – confusion of readers of results, reviewers, and metaanalysts? The infants may need mechanical ventilation for many days. Do we have enough oximeters? Gunnar adds: there is a lot of studies going on in extremely preterms, so there might be competition regarding the infants, although the protocol will accept participant in any other trial, except if there is conflict of protocols.

An e-mail regarding a vote will be sent out.

How should we integrate the SafeBoosC-III result in the article?

It should be integrated in the introduction section but the issue is how. So far it has not been mentioned, as the SafeBoosC-III publication was not out yet. Maria will draft the inclusion since we expect the result paper to be out before submission of the protocol paper manuscript.

Follow-up: Flowchart from the PlaNet-2 – would this be possible in your country?

No direct comments on the PlaNet-2 flowchart but Gene stated that it is very important that we put an effort in the consent form and that contact with the parents is already established during enrolment. Many of these infants will not have routine follow-up at two years of age and will therefore not come into the clinic so contact must be established and maintained at enrolment. Gorm mentioned that it must be possible to get contact with the parents through other channels of the health care system if the infants already have consented for the two year follow-up. Gunnar said that they will have e-mail addreses on the parents which will be a good way to maintain contact. Maria said that we will discuss this further later on.

Any other business

It was decided that steering group meetings will be held every six months, unless funding is obtained for the IIIv trial, or other important matters arise.

Meeting ended at 21:28