Minutes from the SafeBoosC Steering Committee Meeting the 10th of November 2021

Present: Ebru Ergenekon, Hans Fuschs, Jakub Tkaczyk, Maria Vestager, Adelina Pellicer, Gorm Greisen, Mathias Lühr Hansen, Marie Rasmussen, Christian Gluud, Monica Fumagalli, Janus Christian Jakobsen, Gunnar Naulaers, Gene Dempsey, Siv Fredly

Apologies: Jonathan Mintzer, Saudamini Nesargi, Simon Hyttel-Sørensen, Tomasz Szczapa

Absent: Guoqiang Cheng, Ana Vilan, Anne Marie Heuchan, Gerhard Pichler, Gabriel Dimitriou

Trial status update from Copenhagen

As of the 10th of November, a total of 1505 participants have been randomised across 73 centers. Sixtynine of these centers have randomised at least one participant. We expect this to be the final number of participating centers. The randomisation rate the last month has been 2,9 per day, which is higher than the previous month. If everything progresses accordingly, we should reach our goal of 1600 randomisations around Christmas time.

Secondary publications

Gorm and Mathias presented the plan for secondary publications. It is proposed that all PIs may plan and conduct secondary studies/publications, however, must be approved by the steering committee. Minimum requirements will be 1) a specific, well-defined, quantitative hypothesis, 2) a power calculation. Principal investigators should present the proposed studies at the investigator meeting in March 2022. Herafter the steering committee will discuss the proposed studies and decide on a secondary publication plan, which will be published on the website. It is emphasized that we should encourage PI's to define and register secondary analysis on Clinicaltrials.gov before the results of the primary analysis are known. There will also be a possibility to define secondary studies after the publication of the primary outcome, as this may reveal some results that need further investigation. Finally, it was discussed that the secondary studies should not be submitted for publication before publication of the primary analysis.

The formal decision on the proposed model for secondary publications will be taken on the next steering committee meeting in January. A revised model with more details will be sent out beforehand.

The SafeBoosC-III follow up study – a status

Four centers have participants who have reached two years of corrected age, and all these centers have started completing data entries in OpenClinica. A total of six participants have been followed up. The parental questionnaire is also being filled out by families. The start of the follow up study has been smooth and so far without any major difficulties. Gorm shared some experience with data entries from Copenhagen, where there is need for additional consent to use data from health care records, since the consent form from randomisation did not include the follow up study. Thus, we encourage PIs to see if there may be similar problems their center, and if so to find ways to address them. Under "other standardised neurodevelopmental test" in OpenClinica, there has been added a field asking if the score is below the normal range. This is a way to include all neurodevelopmental testing, as there are many test done locally, and this will allow us to simplify the calculation of the binary outcome.

The SafeBoosC-IIIv trial – a status

The protocol will be admitted for ethics approval within the next week and thereafter the design paper will be drafted. We will receive the decision from the Novo Nordisk foundation in December regarding the grant for SafeBoosC-IIIv. If the funding is granted, we plan on starting quickly hereafter and are hopeful to randomise the first patient in late spring/early summer.

No further business