

Minutes from discussions from the 3rd SafeBoosC-III investigator meeting 19-20th of May, 2022

During the session 1, 'Unblinding of abstract and discussion' as well as session 2, 'Round-up from yesterday' results from the SafeBoosC-III trial were discussed and it has been decided to keep the results confidential until the results have been published or presented at the EAPS congress in October. Therefore minutes from these discussion will not be available in public space and will only be available to co-authors of the main publication. Furthermore the results were discussed in the session on the SafeBoosC-IIIV trial, therefore discussions in this session will also be kept confidential. Please contact Marie (marie.isabel.skov.rasmussen@regionh.dk) or Mathias (mathias.luehr.hansen@regionh.dk) if you are a co-author and wish to receive the minutes from the confidential sessions.

Sessions 2, 'Follow up of children' and 'SafeBoosC-III follow up study' 10:20-14:30 20th of May

Present virtually: Christian Gluud, Monica Fumagalli, Ebru Ergenekon, Adelina Pellicer, Merih Cetinkaya, Karen McCall, Rebeca Sanchez Salmador, Salvador Piris, Gerhard Pichler, Asli Memisoglu, Tanja Karen, Anne Marie Heuchan, Camilla Fontana, Thais Agut, Malaika Cordereio

Present physically: Chantal Lecart, Liebeth Thewissen, Pierre Maton, Gunnar Naulaers, Gene Dempsey, Mariana Baserga, Zuzana Matejkova, Peter Korcek, Jakub Tzackub, Ruth del Rio, Miguel Alsina, Luis Arruza, Isabel de las Cuevas, Begona Loureiro, Tomasz Szczapa, Evangelia Papatoma, Simon Hyttel-Sørensen, Kosmas Sarafidis, Gabriel Dimitriou, Maria Vestager, Markus Harboe Olsen, Gorm Greisen, Mathias Lühr Hansen, Marie Rasmussen, Janus Christian Jakobsen

PARCA-R - challenges in international application – Samantha Johnsen

It is asked if there is a difference in the scores when the parental questionnaires are filled out by the parents independently versus if the clinician supports the parents in filling it out in the follow up clinic. Samantha does not have any data on this.

Priorities, choice of data, and practical issues for IIIfu – Marie Rasmussen

Gorm emphasises importance of blinding, Chantal Lecart mentions that it might be difficult to find a blinded person, since all in the clinic are involved in clinical care. Marie says that blinded assessor may be found outside the clinic itself, it just needs to be a competent staff member, some centres have found a solution for this – they will present later. Marie states that classification based on clinical records will sometimes be a subjective assessment and therefore it can bias the assessment to be unblinded.

Experiences from organising the IIIfu work in hospitals

Asli Memisglu – Turkey

The routine follow-up is very well structured but done by many clinicians and work plans are settled every months. The clinicians are blinded to randomisation. The PI will provide the data required for OpenClinica on paper for the clinician of the day and check and if not completed then follow-up on phone. The neurodevelopmental assessment used in Aslis center is the Denver II.

Zuzana Matejkova – Czech Republic

Zuzana asks how and who should assess the question regarding chronic health problems – answer: If there is a diagnosis by a doctor of a disease lasting more than a few months, affects daily life and carries a long time risk then yes. In case of isolated failure to thrive in terms of a slow catch up of weight but with no identified cause and otherwise reasonably healthy, Gorm would not diagnose it as a chronic health problem since such

is common in young childhood, and although there may be an increased risk of cardiovascular or metabolic disease in adult life, this is uncertain when it comes to late infancy growth restriction. It is a challenge that the ophthalmologists do not write mod-or-severe vision impairment but just note a dioptre, Zuzana needs to figure out how to dichotomize the severity level, may discuss with ophthalmologists.

Isabel de las Cuevas – Spain

Due to flight changed had to leave early and did not get the possibility to present.