Blinding Procedure of Follow-up and Data Entry on SafeBoosC III of Marmara University

Asli Cinar Memisoglu (PI)

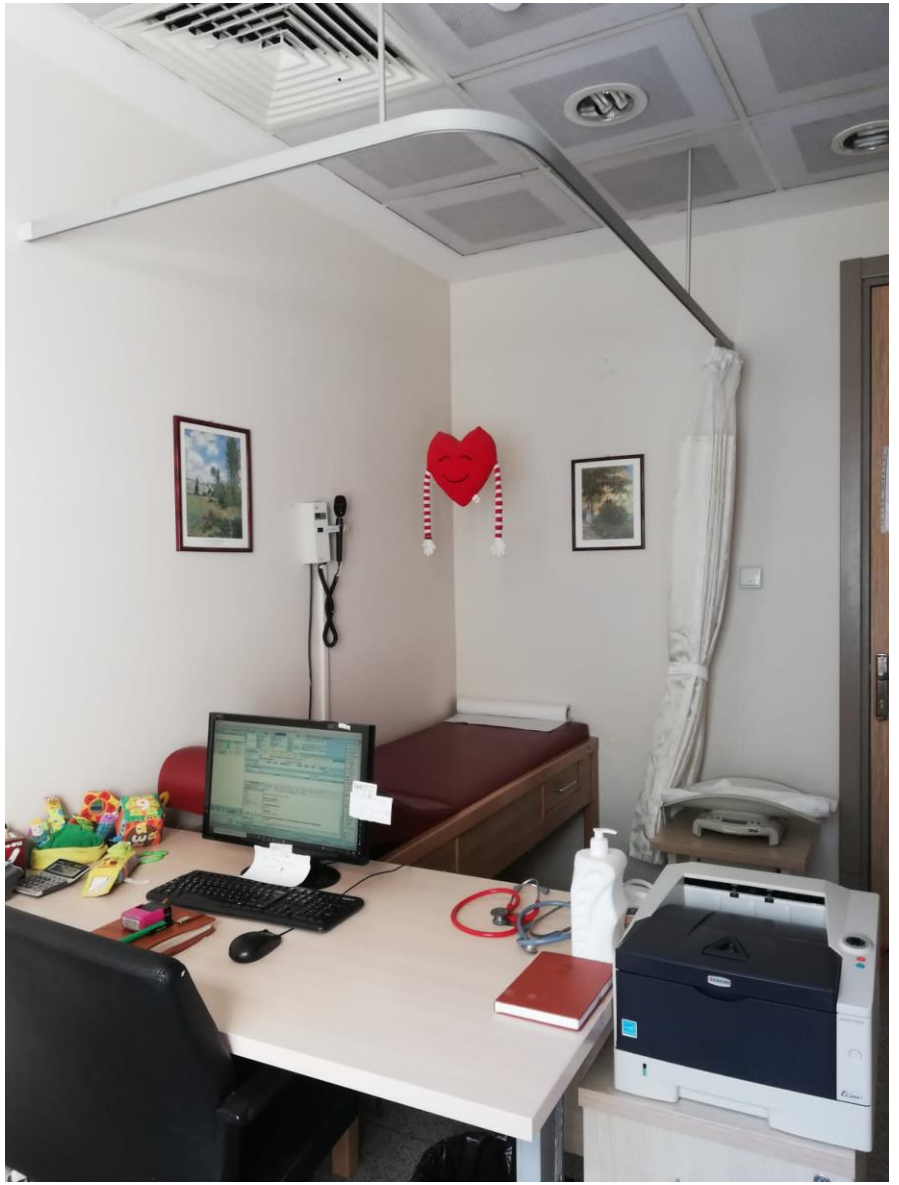
MARMARA UNIVERSITY

Istanbul

Greetings from Istanbul

SafeBoosC III investigators

- **Asli Cinar Memisoglu** (Principal investigator)
- **Sinem Gulcan Kersin** (Second Investigator)
- **Eren Ozek** (Mentor, Head of Nenatology)



General information on our division of Neonatology

- NICU: Level 4 (25 beds)
- Includes maternity ward and one follow-up clinic
- Inborn and outborn neonates
- The average annual number of births is around 2000 in our hospital.
- The average annual number of inpatients in NICU is around 500.
- Two senior attending faculty members
- Two junior attending faculty members
- Three neonatologists
- Pediatrics residents (8)

SafeBoosC III

- Total 33 neonates
- Exitus: 9
- One patient was the baby of an Ethiopian mother who began to labour during an airport transfer. He was discharged but did not come to follow-up.

Our main challenges

1. Staff shortage
2. Lack of Bayley III test and performer
3. The region where our hospital is located and served is a region that is relatively socioeconomically below the city average and where many refugees live. (problems in terms of both communication and uninterrupted follow-up examinations.

Blinding procedure

- All the survived infants enrolled in the SafeBoosC III study are included in the routine clinical FU provided by our unit.
- The principal investigator (PI) will verify the follow-up dates of each infant included in SafeBoosC III FU.
- PI is not involved in the infants' follow-up assessments.

Blinding procedure

- In Marmara University's hospital, extremely preterm infants are followed up according to our institutional protocol when they reach 40 weeks of postmenstrual age (PMA), 2, 3, 6, 9, 12, 18 and 24 months of corrected age (CA).
- In addition, they are consulted at the Pediatric Neurology Clinic at 3, 6, 9, 12, 18 and 24 months of CA.
- The Denver II Developmental Screening Test is applied by a child development specialist at 6, 9, 12, 18 and 24 months of CA.

Blinding procedure

- As per our unit protocols, the extremely preterm babies' first follow-up visits are scheduled just before discharge. These FU visits include eye examination (ROP) follow-up visits, automated Auditory Brain Response (ABR) hearing testing, visits to the High-Risk Neonate Follow-up clinic, Physiotherapy clinic and Pediatric Neurology outpatient clinic.

- Within 2-3 days after discharge, the infant is brought to the High-Risk infant follow-up clinic. A senior pediatric resident or pediatrician, who rotates every month, works for only one month in this follow-up clinic. If necessary, the resident informs and consults the Neonatology specialist in charge. «Due to the staff limitation, either a senior pediatric assistant or pediatrician who will work in this clinic every month is determined by the Pediatrics Department at the end of each month. Therefore, it is not possible to predict who will work in this clinic beforehand.»

Blinding procedure at 24 months of CA

- SI will contact families by email or phone to ensure that patients come to their corrected 24-months of CA follow-up visits.
- Apart from this, SI will not attend the follow-up visit, will not meet with the parents, and will not participate in any assessment of the patient.
- Before the FU visit, she will provide the pre-printed forms (including data requested on eCRF and the web address of the online questionnaire to be filled by the parents) and remind the rotational resident oorking in the FU clinic f all the standard tasks for the FU study.
- These pre-printed forms will be filled out by the resident afterwards.

Blinding procedure

- At the FU visits, the doctors open a new visit every time the child comes for a follow-up visit, so they do not enter into the first admission records (this should be an intended action).
- So, no risk to unblind.
- In the hospital EPR system, there are only clinical records regarding SafeBoosC group allocation at the beginning of the infants's stay and during the intervention, if in the experimental group (first 72h).
- Just before the infant is discharged, a document regarding the summary of the clinical course is edited without mentioning the trial.

Blinding procedure

- During the visit, the resident checks that the baby's necessary neurology, eye, hearing, Denver test and physical therapy assessments have been completed.
- If she/he detects a deficiency in these assessments, he reaches the physicians in the relevant clinics by phone and sets up an appointment to be made within the next few days if possible.
- She/he records the results of these evaluations on forms provided by **SI** beforehand.
- By reading and understanding the questionnaire, the resident can assist the parent in filling out the "pre-printed parental questionnaire" for the baby.

Blinding procedure

- At the end of the follow-up visit, **SI** will collect the completed documents from the resident and check whether there are any missing items, then pass them on to the **PI** for entry into the eCRF.

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c. **Gorm Greisen,** Coordinating investigator of the SafeBoosC-III study, Department of Neonatology, Copenhagen University Hospital

d. **Ebru Ergenekon,** National coordinator of the SafeBoosC-III study of Turkey, Department of Neonatology, Gazi University Hospital