

## SafeBoosC-III newsletter July 2020

Dear investigators

Welcome to the July 2020 issue of the SafeBoosC-III newsletter.

### **Practical issues with monitoring the smallest babies**

During the last month, there have been two incidences in Poland and one in Spain, where they were not able to get a signal with the Oxyprem sensor when monitoring the smallest babies with small head circumference. In Poland, the babies were not randomised and in Spain, the baby was randomised to the experimental group, but the staff eventually gave up on monitoring.

This was discussed at the latest steering committee meeting, where other national coordinators also reported issues with getting a signal on the smallest babies when using the Oxyprem sensor. However, Oxyprem has developed a bending aid, which enhances the curvature allowing better contact between the sensor and the head, Which Gorm reported to have good experience with.

It was agreed at the meeting, that it is up to the individual doctor whether they will randomise a baby if they suspect that it will be difficult due to the small head circumference. As an alternative, the baby can be randomised, and if in the experimental group, monitored as well as possible, potentially by hand-held ‘spot’ measurements when clinically indicated. The argument is that this is a pragmatic trial, testing the effect of the intervention in a real-world situation and such difficulties is part of the usage of NIRS monitoring and thus, it should be dealt with as decided by individual doctors. The protocol will not be changed.

### **Minutes from steering committee meeting**

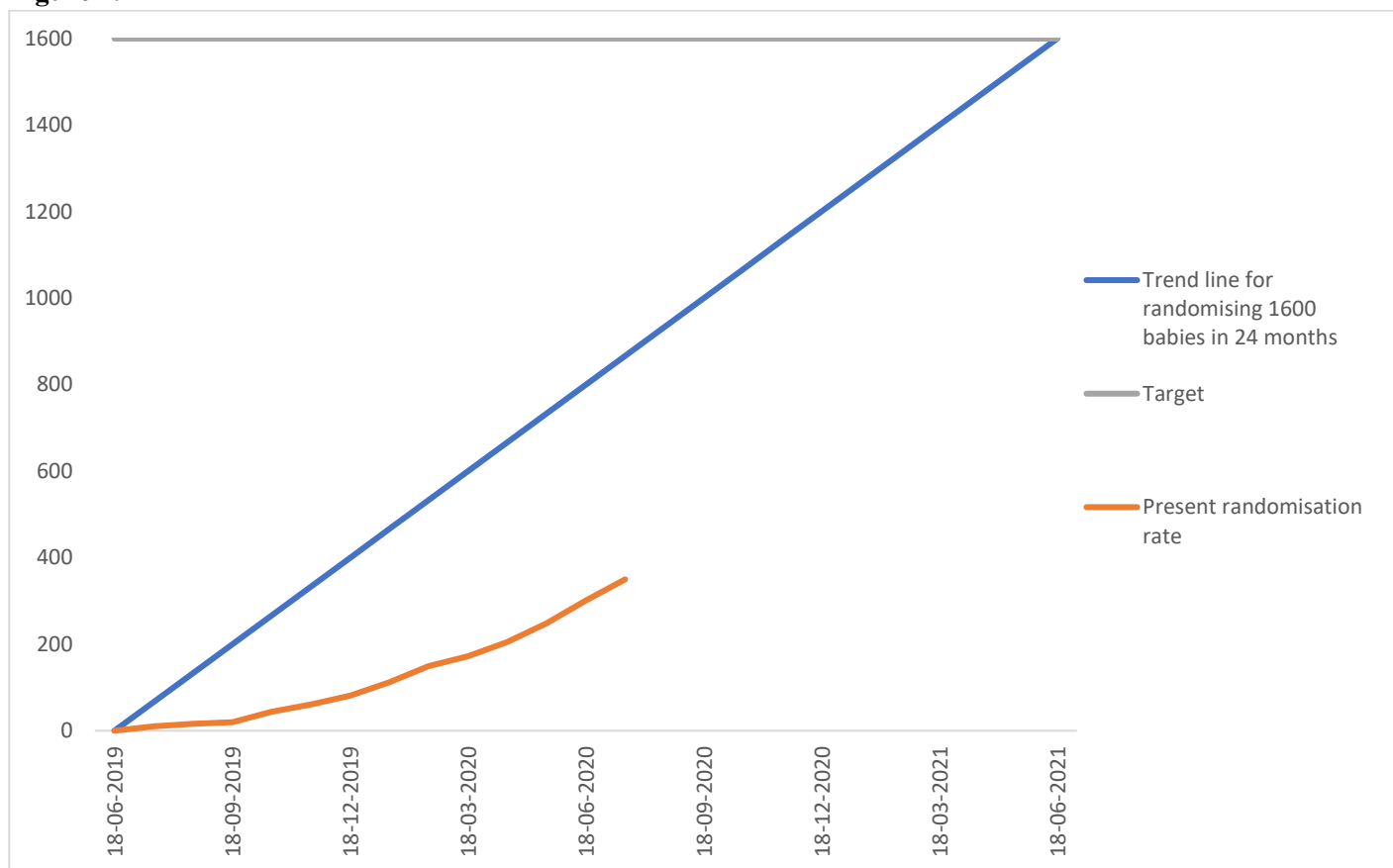
The eighth steering committee was held through Zoom on the 20<sup>th</sup> of July. The minutes from the meeting can be found in the link below:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/minutes-from-safeboosc-iii-steering-committee-meeting.pdf>

### **Status on randomisations and trial preparations**

As of the 18<sup>th</sup> of July, a total of 351 babies have been randomised, which is a slight decrease in the randomisation rate as compared to last month (**figure 1**). At the same time, the number of hospitals opened up for randomisation has increased from 46 to 48. This was discussed during the latest steering committee meeting, where several national coordinators reported that the rate of extremely preterm births is still lower than usual, most likely as a result of the COVID-19 outbreak. Thus, there is confidence that the randomisation rate will increase shortly and that the pandemic, all things considered, has had a minor impact on SafeBoosC III.

**Figure 1.** Randomisation rate in the trial



In **table 1** below, you will find an overview of the randomisations in each of the 48 open hospitals.

**Table 1.** Open hospitals and randomisations up until 18th of July 2020.

Country	Centre	Randomised since	Randomisations
<b>Austria</b>	University Hospital Graz	June 2020	0
<b>Belgium</b>	UZ Leuven	June 2020	8
<b>Belgium</b>	Liege Rocourt	July 2020	0
<b>Belgium</b>	Grand Hospital de Charleroi	July 2020	1
<b>Czech Republic</b>	The Institute for the Care of Mother and Child	Sep 2019	20
<b>China</b>	Children’s Hospital of Zhejiang, Hangzhou	Jan 2020	0
<b>China</b>	Children’s Hospital of Fudan University, Shanghai	Jan 2020	12
<b>China</b>	Hainan Women and Children’s Medical Center	Mar 2020	0
<b>China</b>	Guangzhou Women and Children’s Medical Center	Mar 2020	1

Country	Centre	Randomised since	Randomisations
China	Longgang District Central Hospital of Shenzhen	May 2020	0
China	The People's Hospital of Dehong	May 2020	0
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	0
China	Xiamen Children's Hospital	May 2020	0
Denmark	Rigshospitalet	Jun 2019	49
Denmark	Odense University Hospital	Dec 2019	3
Denmark	Aalborg University Hospital	Mar 2020	0
Denmark	Aarhus University Hospital	May 2020	2
Germany	Freiburg University Hospital	June 2020	0
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	13
Greece	University of Patras General Hospital	Jan 2020	5
Greece	Alexandra Univ. Hospital	March 2020	6
Greece	University Hospital of Heraklion	March 2020	4
India	St Johns Medical College Hospital, Bangalore	June 2020	0
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	14
Poland	Medical Center UJASTEK, Krakow	Jan 2020	9
Poland	Poznan University of Medical Sciences	Mar 2020	5
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	2
Poland	Wroclaw Medical University	Apr 2020	0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	7
Spain	La Paz University Hospital	Jul 2019	27
Spain	Hospital Clinic de Barcelona	Jul 2019	27
Spain	University Hospital 12 de Octubre	Jul 2019	27
Spain	Hospital de Sant Joan de Deu	Oct 2019	14
Spain	Hospital Clinico San Carlos	Sep 2019	12
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	11
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	6
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	3
Spain	C. U. Universitario de Santiago	Jan 2020	0
Spain	Hospital Miguel Servet	Apr 2020	0
Switzerland	Zürich University Hospital	Dec 2019	10
Switzerland	Luzerner Kantonsspital	Jan 2020	9
Switzerland	Geneva University Hospital	May 2020	4
Turkey	Gazi University Hospital	Jan 2020	5

Country	Centre	Randomised since	Randomisations
Turkey	Marmara University Hospital	Jan 2020	8
Turkey	Uludag University Hospital	Jan 2020	3
Turkey	Kanuni Sultan University Hospital	Jan 2020	10
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	14
United States	University of Utah	June 2020	0
<b>Total</b>			351

### **Delay on data completion report**

Due to technical issues and a data manager on holidays we will not be able to conduct and write the central monitoring report for July 2020 until the beginning of August.

Once the report has been completed, investigators with missing data entries will be contacted and urged to complete data entries.

As for developing a method to timely detect major differences in data among hospitals, we are in the final phase of writing the data monitoring plan and will inform you as soon as it is completed.

Thank you for your time,  
 Best wishes  
 Gorm and Mathias