

## SafeBoosC-III newsletter January 2021

Dear investigators

Welcome to the January 2021 issue of the SafeBoosC-III newsletter.

### **Launch of the SafeBoosC-III app**

We are happy to announce the launch of the SafeBoosC-III app. The app is now available on both Android and Apple phones, by searching *SafeBoosC* in Google Play or App Store, respectively.

The app is designed for clinicians involved in the randomisation and care of participants in SafeBoosC-III. It is meant as a convenient handbook to answer urgent trial related questions such as eligibility criteria, treatment guideline, common OpenClinica questions, hypoxic thresholds and contact information for the emergency randomisation. It is not possible to randomise directly from the app. No user registration is required and furthermore, no data is collected from the app. If you and your staff have any feedback regarding the app, do not hesitate to reach out.

Please find QR codes below to scan for direct download.

App Store (iPhone):

Google Play (Android):



### **Update on the SafeBoosC-III two-year follow-up study**

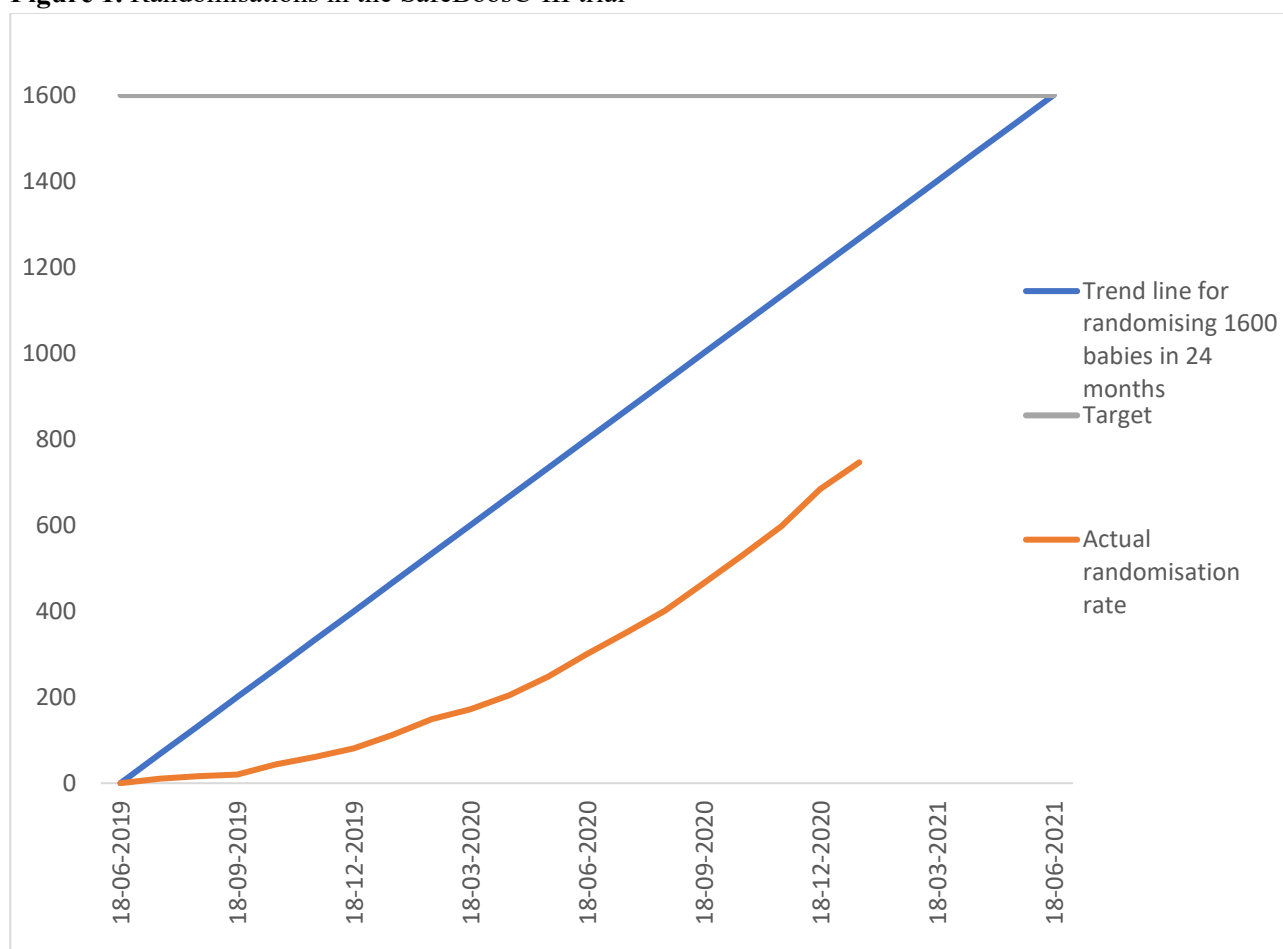
Preparations for the SafeBoosC-III two-year follow up study are progressing. Marie Rasmussen will be the project manager/PhD student of the study. The outcome measures will rely on routine follow-up data in combination with the PARCA-R questionnaire. An online platform for the distribution of the PARCA-R questionnaire, in 17 languages, will be developed. Two-year follow-up assessments will begin in the late fall of 2021. The steering committee has agreed that a follow-up percentage of 75% of surviving children is required to obtain co-authorship. An official invitation to participate in the follow-up study will be sent out shortly.

### Status on randomisations and trial preparations

As of the 18<sup>th</sup> of January, a total of 746 babies have been randomised across 62 centres. Thus, the randomisation rate of January is lower than in the previous months (2.02 randomised babies per day in September, 2.17 in October, 2.19 in November, 2.87 in December and 2.0 in January) (**figure 1**). We do not know the exact reasons to this decrease. However, some investigators have reported that all research in their centre have been put on hold due to the second wave of COVID-19. It might also be due to normal variation, unrelated to COVID-19 or other specific events. Let us hope that the randomisation rate will increase again by February!

As mentioned above, 62 centres are actively randomising and an additional 9 centres are expected to start randomising within 1<sup>st</sup> of March as well.

**Figure 1.** Randomisations in the SafeBoosC-III trial



In **table 1** below, you will find an overview of the randomisations in each of the 62 open hospitals up until 18<sup>th</sup> of January 2021. Additionally, we have added a new column, “randomisations per month”, which provides an overview of the average number of randomisations per month for each hospital during the time period, where the hospital has been open for randomisation.

**Table 1.** Open hospitals, randomisations and average randomisations per month per hospital up until 18th of January 2021.

Country	Centre	Randomised since	Randomisations	Randomisations per month
Austria	University Hospital Graz	Jun 2020	7	1
Belgium	UZ Leuven	Jun 2020	17	2.4
Belgium	Liege Rocourt	Jul 2020	2	0.3
Belgium	Grand Hospital de Charleroi	Jul 2020	5	0.8
Belgium	AZ St. Jan University Hospital Brugge	Sep 2020	5	1.3
Belgium	CHU Tivoli	Sep 2020	7	1.75
Belgium	Liege Citadelle Hospital	Nov 2020	0	0
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	38	2.4
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	31	2.6
China	Hainan Women and Children's Medical Center	Mar 2020	0	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	2	0.2
China	Longgang District Central Hospital of Shenzhen	May 2020	5	0.6
China	The People's Hospital of Dehong	May 2020	3	0.4
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	5	0.6
China	Xiamen Children's Hospital	May 2020	2	0.3
Denmark	Rigshospitalet	Jun 2019	68	3.6
Denmark	Odense University Hospital	Dec 2019	6	0.5
Denmark	Aalborg University Hospital	Mar 2020	5	0.5
Denmark	Aarhus University Hospital	May 2020	9	1.1
Germany	Freiburg University Hospital	June 2020	6	0.9
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	21	1.4
Greece	University of Patras General Hospital	Jan 2020	8	0.7
Greece	Alexandra Univ. Hospital	Mar 2020	12	1.2
Greece	University Hospital of Heraklion	Mar 2020	7	0.7

Country	Centre	Randomised since	Randomisations	Randomisations per month
India	St Johns Medical College Hospital, Bangalore	Jun 2020	3	0.4
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	Nov 2019	26	1.9
Italy	Presidio Ospedaliero S. Anna, Turin	Aug 2020	1	0.2
Italy	Ospedale Fillipo del Ponte, Varese	Oct 2020	2	0.7
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	Dec 2020	0	0
Poland	Medical Center UJASTEK, Krakow	Jan 2020	23	1.9
Poland	Szpital Uniwersytecki, Kraków	Oct 2020	4	1.3
Poland	Warsaw University of Medical Sciences	Oct 2020	3	1
Poland	Poznan University of Medical Sciences	Mar 2020	23	2.3
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	3	0.3
Poland	Wroclaw Medical University	Apr 2020	0	0
Poland	Jan Biziel University Hospital	Sep 2020	0	0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	11	1
Spain	La Paz University Hospital	Jul 2019	55	3.1
Spain	Hospital Clinic de Barcelona	Jul 2019	37	2.1
Spain	University Hospital 12 de Octubre	Jul 2019	36	2
Spain	Hospital de Sant Joan de Deu	Oct 2019	21	1.4
Spain	Hospital Clinico San Carlos	Sep 2019	22	1.4
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	17	1.1
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	11	0.8
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	6	0.5
Spain	C. U. Universitario de Santiago	Jan 2020	0	0
Spain	Hospital Miguel Servet	Apr 2020	0	0
Switzerland	Zürich University Hospital	Dec 2019	30	2.3
Switzerland	Luzerner Kantonsspital	Jan 2020	26	2.2
Switzerland	Geneva University Hospital	May 2020	7	0.9
Switzerland	Lausanne University Hospital	Sep 2020	9	2.3
Turkey	Gazi University Hospital	Jan 2020	7	0.6
Turkey	Marmara University Hospital	Jan 2020	15	1.3
Turkey	Uludag University Hospital	Jan 2020	17	1.4

Country	Centre	Randomised since	Randomisations	Randomisations per month
Turkey	Kanuni Sultan University Hospital	Jan 2020	11	0.9
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	28	2.3
Turkey	Basaksehir City Hospital	Jan 2021	1	1
United States	University of Utah, Division of Neonatology	Jun 2020	7	1
United states	Loma Linda University Hospital	Sep 2020	13	3.3
United States	UT Southwestern Medical Center, Dallas	Oct 2020	0	0
<b>Total</b>			746	

### Data completion monitoring report

In the link below you will find the central monitoring report regarding data completion from January 2021.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-18-dec-2020.pdf>

For the end of monitoring and follow-up form, completion of data entries is still good with 97% completion. Completion of the blinded follow-up form has slightly decreased from 89% last month to 87% this month. Thus, there is still room for improvement, as we aim for less than five percent missing data.

Completion of the SAR form is 92% this month, which is the same in December. As with the blinded follow-up form, we hope that the completion of the SAR form, will improve within the next couple of months.

Once again, we would like to state that timely reporting is an important part of the quality of the trial and thus we hope you will prioritize these data entries despite your busy daily schedule.

Investigators with missing data entries have been contacted and urged to complete data entries.

### Minutes from the 11th steering committee meeting

The eleventh steering committee meeting was held over Zoom on the 25<sup>th</sup> of January. Minutes from the meeting, including the agenda, can be found here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/minutes-from-sc-meeting-25th-of-january-2021.pdf>

Best wishes

Gorm, Marie and Mathias