

SafeBoosC-III newsletter August 2020

Dear investigators

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

COVID-19 SafeBoosC study

Several of you have reported a decline in the number of admitted extremely preterm infants in your hospital during the COVID-19 pandemic, while others have reported no change, or even an increase. A dramatic decrease has been reported in two studies from Denmark and Ireland, respectively. However, the numbers in these studies were small.

Since the SafeBoosC consortium constitutes a large number of neonatologists from different NICUs worldwide, we see a possibility to estimate the magnitude of a decline with a reasonable precision.

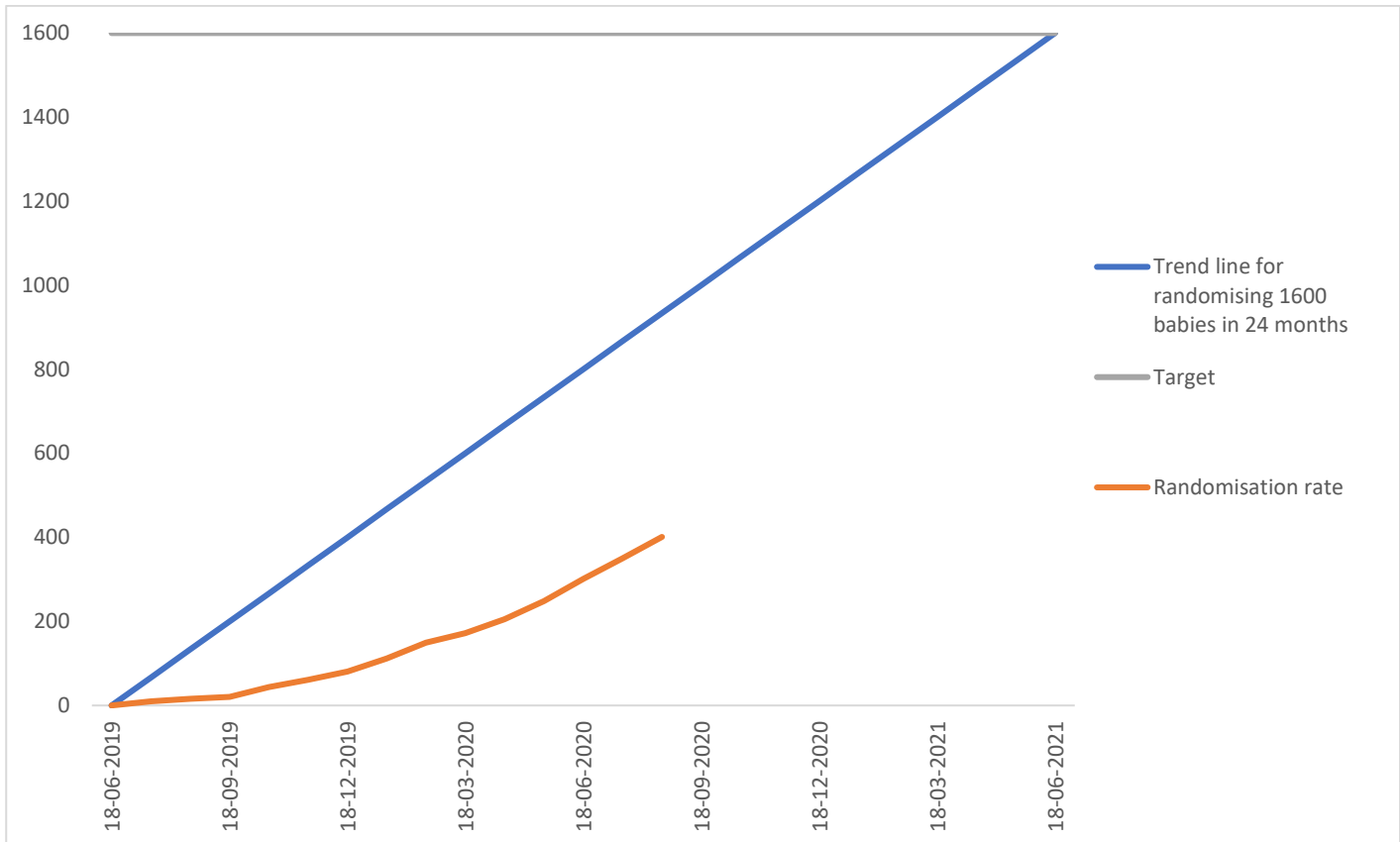
We have therefore designed a study, evaluating if the number of admitted extremely preterm infants during the peak of COVID-19 has changed on a global scale, when compared to the same period last year. Furthermore, we also want to explore if there is a correlation between the number of admitted extremely preterm infants and the level of local or national lockdown restrictions.

You will all be invited to participate and co-author this study. Invitations, including a study synopsis and a questionnaire will be sent out within the next couple of days.

Status on randomisations and trial preparations

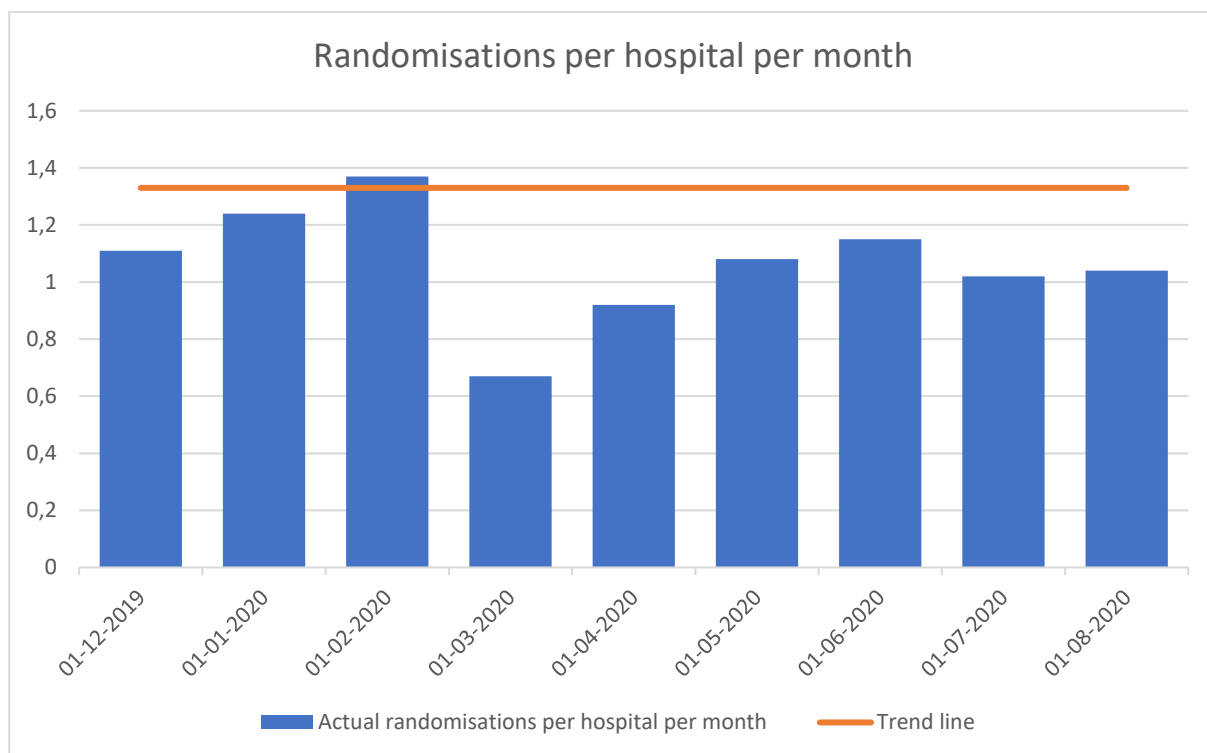
As of the 18th of August, a total of 401 babies have been randomised. which is a slight increase in the randomisation rate as compared to last month (1.65 randomised babies per day compared to 1.63 randomised babies per day) (**figure 1**). At the same time, the number of hospitals open for randomisation has increased from 48 to 49, meaning that we have (almost) reached our initial goal of 50 hospitals open for randomisation.

Figure 1. Randomisation rate in the trial



However, as can be seen in **figure 2**, the randomisation rate per hospital has stagnated the last couple of months – and we are still far from the expected hospital randomisation rate of 1.33 babies per month (present rate is 1.04 baby per hospital per month). We are aware that COVID-19 still might affect the trial execution, especially with COVID-19 numbers slowly increasing in Europe again. During the next steering committee meeting on 21st of September, we will discuss trial execution country-by-country and whether things can be done to improve the randomisation rate.

Figure 2. Randomisations per hospital per month.



In **table 1** below, you will find an overview of the randomisations in each of the 49 open hospitals up until 18th of August 2020.

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

Country	Centre	Randomised since	Randomisations
Austria	University Hospital Graz	June 2020	2
Belgium	UZ Leuven	June 2020	6
Belgium	Liege Rocourt	July 2020	0
Belgium	Grand Hospital de Charleroi	July 2020	1
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	25
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	15
China	Hainan Women and Children's Medical Center	Mar 2020	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	1
China	Longgang District Central Hospital of Shenzhen	May 2020	1
China	The People's Hospital of Dehong	May 2020	0
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	1

Country	Centre	Randomised since	Randomisations
China	Xiamen Children's Hospital	May 2020	0
Denmark	Rigshospitalet	Jun 2019	55
Denmark	Odense University Hospital	Dec 2019	3
Denmark	Aalborg University Hospital	Mar 2020	1
Denmark	Aarhus University Hospital	May 2020	2
Germany	Freiburg University Hospital	June 2020	3
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	15
Greece	University of Patras General Hospital	Jan 2020	6
Greece	Alexandra Univ. Hospital	March 2020	7
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
Italy	Presidio Ospedaliero S. Anna, Turin	Aug 2020	0
Poland	Medical Center UJASTEK, Krakow	Jan 2020	9
Poland	Poznan University of Medical Sciences	Mar 2020	7
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	3
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	30
Spain	Hospital Clinic de Barcelona	Jul 2019	29
Spain	University Hospital 12 de Octubre	Jul 2019	29
Spain	Hospital de Sant Joan de Deu	Oct 2019	15
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	7
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	11
Switzerland	Luzerner Kantonsspital	Jan 2020	10
Switzerland	Geneva University Hospital	May 2020	4
Turkey	Gazi University Hospital	Jan 2020	5
Turkey	Marmara University Hospital	Jan 2020	9
Turkey	Uludag University Hospital	Jan 2020	9

Country	Centre	Randomised since	Randomisations
Turkey	Kanuni Sultan University Hospital	Jan 2020	11
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	16
United States	University of Utah	June 2020	0
Total			401

Central monitoring report

In the link below you will find the central monitoring report from August 2020.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-19-aug-20.pdf>

Completion of data entries is still good with 95% completion of end of monitoring module and the follow-up module. However, the completion of the blinded follow-up module has decreased from 93% to 83%. We are aware that completion of the blinded follow-up module requires more work than the other modules, since all images need to be assessed for each baby, before the module can be completed. However, 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.

Thank you for your time,
Best wishes
Gorm and Mathias