

SafeBoosC-III newsletter December 2020

Dear investigators

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

First interim analysis in February 2021

As mentioned previously, the first interim analysis will take place mid-February 2021. Therefore, it is very important that all data is entered on the babies that has reached 36 weeks of postmenstrual age before the analysis takes place. Therefore, we urge all of you to complete data entries in time.

In case you wish to read more, you can find the Data Monitoring and Safety Committee charter on [safeboosc.eu](https://www.safeboosc.eu):

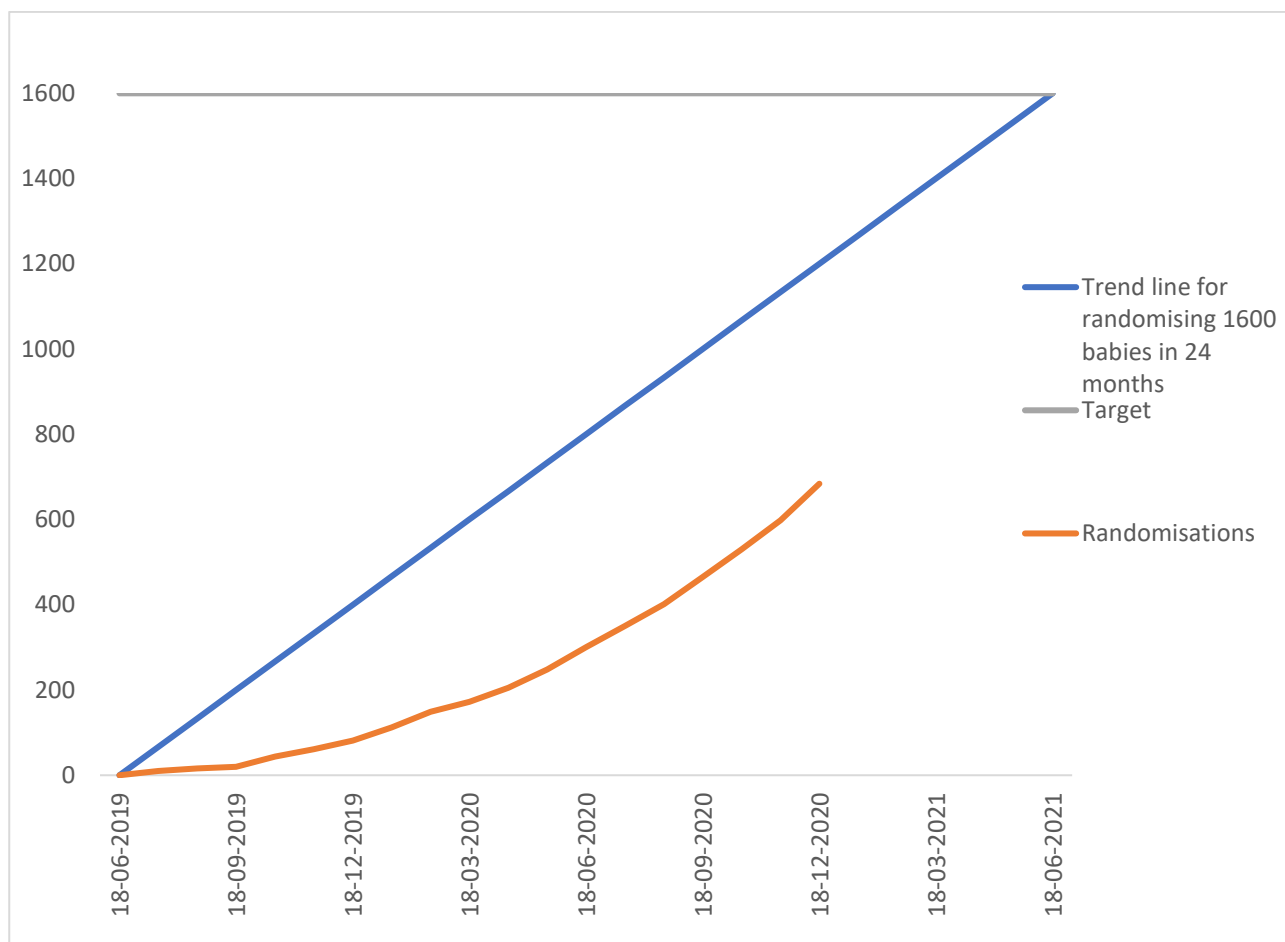
<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Documents/charter-for-the-independent-dmsc.pdf>

Status on randomisations and trial preparations

As of the 18th of December, a total of 684 babies have been randomised. For the fourth month in a row, this is an increase in the randomisation rate (2.02 randomised babies per day in September, 2.17 in October, 2.19 in November and 2.87 in December) (**figure 1**). If we continue with this pace, **we will complete recruitment in November 2021!!**

The number of hospitals open for randomisation has also increased from 59 to 60. We expect this number to increase even more during the next months.

Figure 1. Randomisations in the SafeBoosC-III trial



In **table 1** below, you will find an overview of the randomisations in each of the 60 open hospitals up until 18th of December 2020.

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

Country	Centre	Randomised since	Randomisations
Austria	University Hospital Graz	Jun 2020	7
Belgium	UZ Leuven	Jun 2020	13
Belgium	Liege Rocourt	Jul 2020	3
Belgium	Grand Hospital de Charleroi	Jul 2020	5
Belgium	AZ St. Jan University Hospital Brugge	Sep 2020	4
Belgium	CHU Tivoli	Sep 2020	2
Belgium	Liege Citadelle Hospital	Nov 2020	0
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	36
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0

Country	Centre	Randomised since	Randomisations
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	28
China	Hainan Women and Children's Medical Center	Mar 2020	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	2
China	Longgang District Central Hospital of Shenzhen	May 2020	5
China	The People's Hospital of Dehong	May 2020	1
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	3
China	Xiamen Children's Hospital	May 2020	2
Denmark	Rigshospitalet	Jun 2019	67
Denmark	Odense University Hospital	Dec 2019	6
Denmark	Aalborg University Hospital	Mar 2020	5
Denmark	Aarhus University Hospital	May 2020	8
Germany	Freiburg University Hospital	June 2020	6
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	21
Greece	University of Patras General Hospital	Jan 2020	8
Greece	Alexandra Univ. Hospital	Mar 2020	11
Greece	University Hospital of Heraklion	Mar 2020	6
India	St Johns Medical College Hospital, Bangalore	Jun 2020	2
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	23
Italy	Presidio Ospedaliero S. Anna, Turin	Aug 2020	1
Italy	Ospedale Filippo del Ponte, Varese	Oct 2020	0
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	Dec 2020	0
Poland	Medical Center UJASTEK, Krakow	Jan 2020	20
Poland	Szpital Uniwersytecki, Kraków	Oct 2020	3
Poland	Warsaw University of Medical Sciences	Oct 2020	3
Poland	Poznan University of Medical Sciences	Mar 2020	19
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	3
Poland	Wroclaw Medical University	Apr 2020	0
Poland	Jan Biziel University Hospital	Sep 2020	0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	11
Spain	La Paz University Hospital	Jul 2019	53
Spain	Hospital Clinic de Barcelona	Jul 2019	37

Country	Centre	Randomised since	Randomisations
Spain	University Hospital 12 de Octubre	Jul 2019	35
Spain	Hospital de Sant Joan de Deu	Oct 2019	21
Spain	Hospital Clinico San Carlos	Sep 2019	21
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	15
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	11
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	6
Spain	C. U. Universitario de Santiago	Jan 2020	0
Spain	Hospital Miguel Servet	Apr 2020	0
Switzerland	Zürich University Hospital	Dec 2019	26
Switzerland	Luzerner Kantonsspital	Jan 2020	21
Switzerland	Geneva University Hospital	May 2020	7
Switzerland	Lausanne University Hospital	Sep 2020	6
Turkey	Gazi University Hospital	Jan 2020	6
Turkey	Marmara University Hospital	Jan 2020	14
Turkey	Uludag University Hospital	Jan 2020	15
Turkey	Kanuni Sultan University Hospital	Jan 2020	11
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	28
United States	University of Utah, Division of Neonatology	Jun 2020	7
United states	Loma Linda University Hospital	Sep 2020	9
United States	UT Southwestern Medical Center, Dallas	Oct 2020	0
Total			684

Data completion monitoring report

In the link below you will find the central monitoring report regarding data completion from December 2020.

<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 increasing, with 97% and 98% completion respectively. Completion of the blinded follow-up form has slightly improved from 88% last month to 89% this month. However, there is still room for improvement, as we aim for less than five percent missing data.

The completion of the SAR form has also increased from last month (92% completed SAR forms in December compared to 90% in November).

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.

Data quality monitoring report

The second round of data quality monitoring was conducted on 30th of November. In the link below you will find the report.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-quality-report-30-nov-2020.pdf>

The monitoring reports evaluating data quality will be written every third month and the relevant investigators will be contacted with inquiries.

The full central monitoring plan can be found here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/central-monitoring-plan-safeboosc-iii-260820.pdf>

Thank you for your time,

Best wishes

Gorm and Mathias