

SafeBoosC-III newsletter May 2021

Dear investigators

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

SafeBoosC-III follow-up study

The SafeBoosC-III fu will rely on routine clinical data as well as parental questionnaires. So far, 38 centres have declared interest in participating. We urge investigators to contact Marie (marie.isabel.skov.rasmussen@regionh.dk) to declare participation or raise any concerns or questions. We did not receive a grant from Elsass (Cerebral Palsy foundation) but have applied for a grant from the Innovation Foundation, which we will receive a preliminary answer from this summer. The first babies will reach two years of corrected age this fall, in Spain and Denmark. Marie will be working full time on the study during the fall, to ensure that centres get a good start with the follow up study.

On the last Steering Committee meeting, the protocol was discussed. Based on this, the protocol will be revised and circulated in the Steering Committee again for comments and final approval, before it is sent to the principal investigator, and thereafter ethics committees. The latter is expected in June.

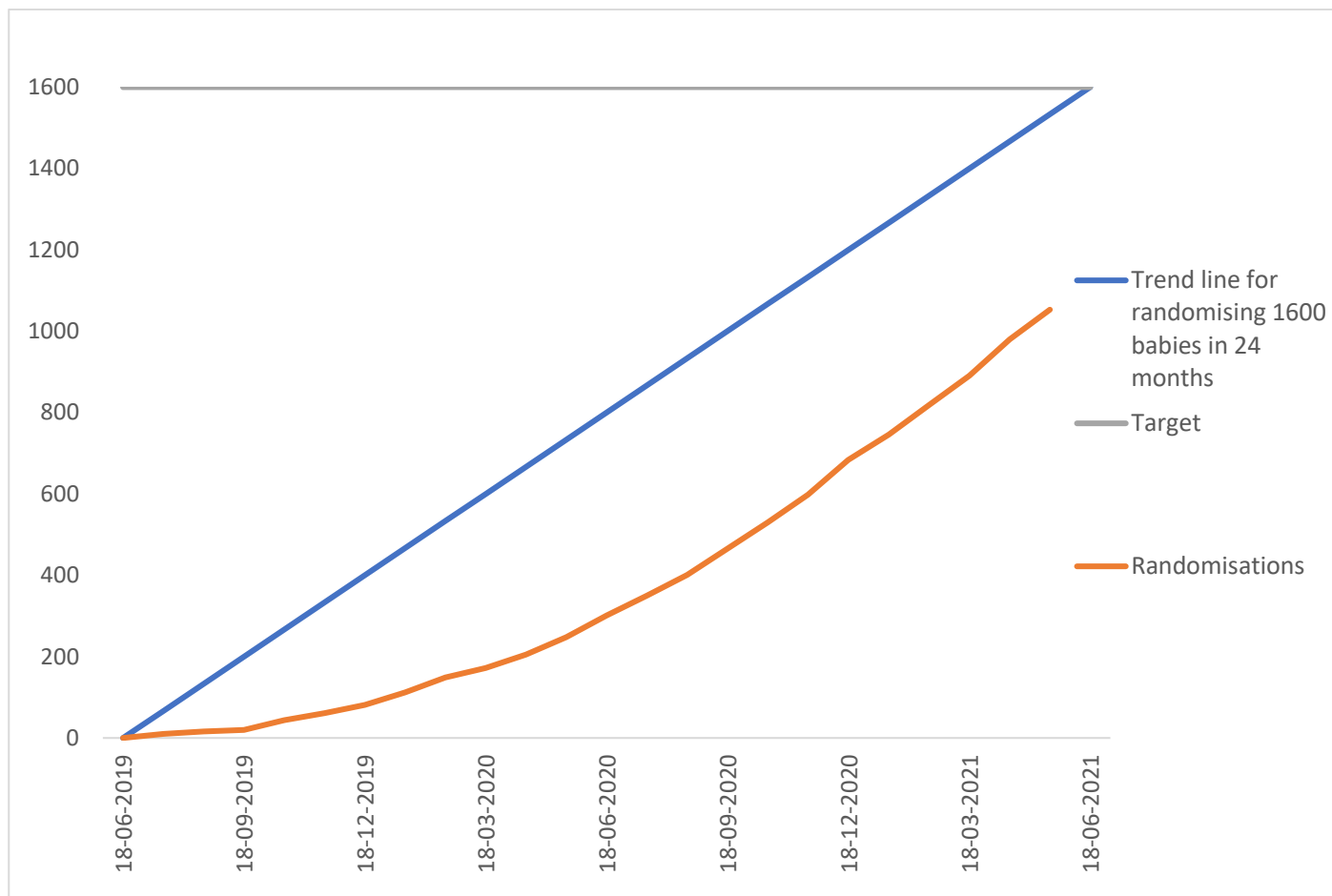
Status on randomisations and trial preparations

As of the 18th of May, a total of 1053 babies have been randomised across 71 centres (fig. 1). This corresponds to 2.4 randomised babies per day, which is a decrease from April's 'all-time high' randomisation rate (2.87 randomised babies per day), but still above the trend line of 2.2 randomised babies per day. The randomisation rate in the trend line is based on 50 randomising centres, which is an average of 1.25 randomised babies per centre per month.

However, as 71 centres are now actively randomising, the present randomisation rate corresponds to 1.03 randomised babies per centre per month, and 37 out of 71 centres are randomising less than 1.25 babies per month.

Based on the randomisation rate from the last three months, we still expect to complete recruitment before the end of 2021.

Figure 1. Randomisations in the SafeBoosC-III trial



In **table 1** below, you will find an overview of the randomisations in each of the 71 centres up until 18th of May 2021. You will also find an overview of the average number of randomisations per month for each centre during the time period, where the hospital has been open for randomisation.

Table 1. Open centres, randomisations and average randomisations per month per centre up until 18th of May 2021.

Country	Centre	Randomised since	Randomisations	Average randomisations per month
Austria	University Hospital Graz	Jun 2020	14	1.3
Belgium	UZ Leuven	Jun 2020	25	2.3
Belgium	Liege Rocourt	Jul 2020	16	1.6
Belgium	Grand Hospital de Charleroi	Jul 2020	6	0.6
Belgium	AZ St. Jan University Hospital Brugge	Sep 2020	9	1.3
Belgium	CHU Tivoli	Sep 2020	13	1.6
Belgium	Liege Citadelle Hospital	Nov 2020	0	0

Country	Centre	Randomised since	Randomisations	Average randomisations per month
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	48	2.4
Czech Republic	Motol University Hospital	February 2021	3	1
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	3	0.2
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	35	2.2
China	Hainan Women and Children's Medical Center	Mar 2020	0	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	2	0.1
China	Longgang District Central Hospital of Shenzhen	May 2020	8	0.7
China	The People's Hospital of Dehong	May 2020	3	0.3
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	7	0.6
China	Xiamen Children's Hospital	May 2020	3	0.3
Denmark	Rigshospitalet	Jun 2019	81	3.6
Denmark	Odense University Hospital	Dec 2019	9	0.5
Denmark	Aalborg University Hospital	Mar 2020	13	0.9
Denmark	Aarhus University Hospital	May 2020	13	1.1
Germany	Freiburg University Hospital	June 2020	9	0.8
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	27	1.4
Greece	University of Patras General Hospital	Jan 2020	9	0.6
Greece	Alexandra Univ. Hospital	Mar 2020	13	0.9
Greece	University Hospital of Heraklion	Mar 2020	8	0.5
India	St Johns Medical College Hospital, Bangalore	Jun 2020	3	0.3
Ireland	University Hospital Cork	February 2021	11	3.7
Ireland	Rotunda Hospital Dublin	May 2021	1	1
Ireland	NMH Holles St	May 2021	0	0
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	Nov 2019	32	1.8
Italy	Presidio Ospedaliero S. Anna, Turin	Aug 2020	5	0.6
Italy	Ospedale Fillipo del Ponte, Varese	Oct 2020	4	0.6

Country	Centre	Randomised since	Randomisations	Average randomisations per month
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	Dec 2020	7	1.4
Norway	Oslo University Hospital	March 2021	6	3
Poland	Medical Center UJASTEK, Krakow	Jan 2020	29	1.8
Poland	Szpital Uniwersytecki, Kraków	Oct 2020	9	1.3
Poland	Warsaw University of Medical Sciences	Oct 2020	8	1.1
Poland	Poznan University of Medical Sciences	Mar 2020	27	1.9
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	5	0.3
Poland	Wroclaw Medical University	Apr 2020	0	0
Poland	Jan Biziel University Hospital	Sep 2020	0	0
Poland	Centre of Medical Postgraduate Education, Warsaw	May 2021	1	1
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	14	0.9
Spain	La Paz University Hospital	Jul 2019	64	2.9
Spain	Hospital Clinic de Barcelona	Jul 2019	44	1.8
Spain	University Hospital 12 de Octubre	Jul 2019	49	2.2
Spain	Hospital de Sant Joan de Deu	Oct 2019	25	1.3
Spain	Hospital Clinico San Carlos	Sep 2019	27	1.4
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	18	0.9
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	16	0.9
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	8	0.5
Spain	C. U. Universitario de Santiago	Jan 2020	0	0
Spain	Hospital Miguel Servet	Apr 2020	0	0
Spain	Hospital de Cruces	Jan 2021	2	0.5
Switzerland	Zürich University Hospital	Dec 2019	37	2.3 (withdrew in May 2021)
Switzerland	Luzerner Kantonsspital	Jan 2020	31	1.9
Switzerland	Geneva University Hospital	May 2020	8	0.7
Switzerland	Lausanne University Hospital	Sep 2020	16	2
Turkey	Gazi University Hospital	Jan 2020	12	0.8
Turkey	Marmara University Hospital	Jan 2020	27	1.7
Turkey	Uludag University Hospital	Jan 2020	26	1.6

Country	Centre	Randomised since	Randomisations	Average randomisations per month
Turkey	Kanuni Sultan University Hospital	Jan 2020	11	1 (withdrew in December 2020)
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	34	2.1
Turkey	Basaksehir City Hospital	Jan 2021	6	1.5
United Kingdom	Royal Hospital for Children, Glasgow	Feb 2021	6	2
United Kingdom	NHS Lanarkshire Hospital, Wishaw	March 2021	4	2
United States	University of Utah, Division of Neonatology	Jun 2020	15	1.5
United states	Loma Linda University Hospital	Sep 2020	25	3.1
United States	UT Southwestern Medical Center, Dallas	Oct 2020	4	0.6
Total			1053	

Data completion monitoring report

In the link below you will find the central monitoring report on data completion from May 2021.

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-25-may-2021.pdf>

For the end of monitoring and follow-up form, completion of data entries is still good with 96% and 98% completion, respectively. Completion of the SAR form has also increased from 92% to 93% month. Unfortunately, the completion of the blinded follow-up form has dropped substantially from 92% to 86% this month. We are unsure why this has happened, but it seems that it is mainly centres with external readers who are lacking behind. This is of course understandable, since such a setup requires extra work (communication with the external assessor, blinding of images, transfer of images etc.).

Again, we would still like to state that timely reporting is an important part of the quality of the trial and thus we hope that all investigators will prioritize these data entries, despite the busy daily schedule.

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

Best wishes

Gorm, Marie and Mathias