

SafeBoosC III newsletter March 2020

Dear investigators

Welcome to the March 2020 issue of the SafeBoosC newsletter.

COVID-19 and SafeBoosC

As COVID-19 continues to spread across Europe and the US, many of the centres participating in SafeBoosC are affected. We have asked the centres already randomising, whether the outbreak will affect their trial activity; a few have had to put the trial on hold for the next couple of weeks, but the majority of centres do not expect the outbreak to affect enrolment. Furthermore, a handful of centres still in the preparation phase, have reported to us that they will not be able to progress with paperwork until the outbreak is under control and offices re-open. Based on this, we expect that SafeBoosC might be delayed due to the epidemic.

However, SafeBoosC III should be resilient to delays due to the decentralised funding, and since the running trial takes few resources, the conflict with other tasks should be small. Some sites, however, have reported, that all clinical trials are put on hold. One other potential problem is that the decentralised monitoring (local GCP) requires visits to the hospital, and this might not be permitted in all hospitals and may be delayed until after the epidemic. With advice from Copenhagen Trial Unit, it is advised to conduct monitoring, whenever it is possible. Every site should report if they are obliged to postpone monitoring and catch up as soon as possible.

In the middle of all this, we have also received good news from China; multiple sites have reported that things are almost back to normal and that they expect to start randomising babies within the next weeks. So far, four Chinese sites have been opened for randomisation. Guoqiang Chieng, national coordinator of China, also reported to us that there has been fewer than ten reported cases of COVID-19 pneumonia in neonates in China and no cases of vertical transmission.

Let us hope that we will back to normal in a few months!

Update to trial documents

A new Standard Operating Procedure named 'Deletion of data in situations with missing or withdrawal of consent' has been uploaded to the website. The purpose of this SOP is to outline when, and how, personal data should be deleted if requested by parents.

This is especially important in cases where a baby is randomised before consent is sought and the parents decline participation once they are asked later (i.e. deferred consent). In such a case, the parents are in their right to decline the use of already collected data.

Direct link to new SOP: <https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/departments-of-neonatology/research/SafeboosC-III/Documents/sop-deletion-of-data-in-situations-with-missing-or-withdrawal-of-consent-270220.pdf>

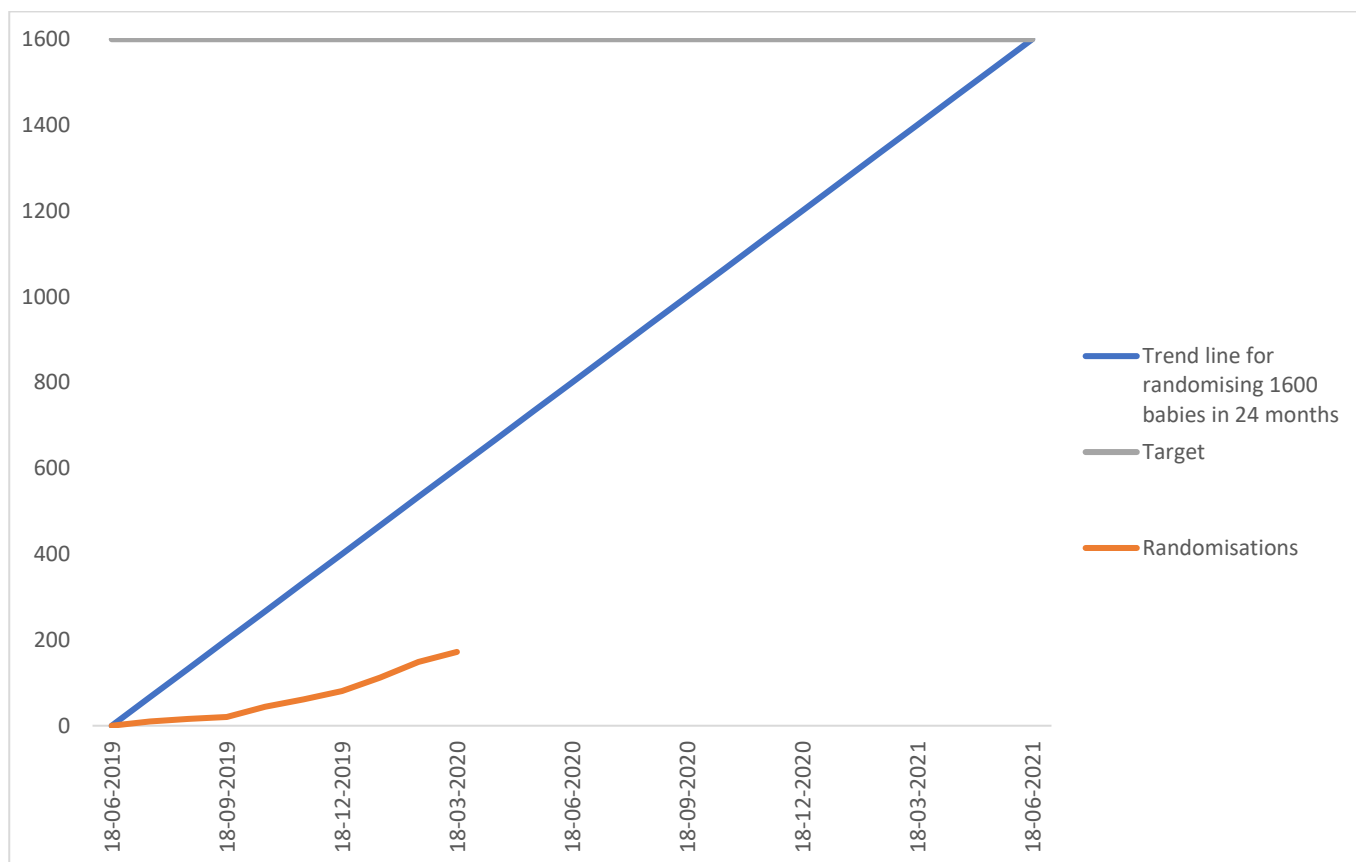
Status on randomisation and trial preparations

As of 22nd of March, we have opened for randomisation in 34 centres and 178 babies have been randomised. Furthermore, 40 additional centres are actively preparing for the trial, meaning they have completed at least one of the trial preparation tasks. Below you will find an overview of randomisations in each of the 34 open centres.

Country	Centre	Randomised since	Randomisations
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	13
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	0
China	Hainan Women and Children's Medical Center	Mar 2020	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	0
Denmark	Rigshospitalet	Jun 2019	37
Denmark	Odense University Hospital	Dec 2019	0
Denmark	Aalborg University Hospital	Mar 2020	0
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	7
Greece	University of Patras General Hospital	Jan 2020	0
Greece	Alexandra Univ. Hospital	March 2020	0
Greece	University Hospital of Heraklion	March 2020	0
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	7
Poland	Medical Center UJASTEK, Krakow	Jan 2020	4
Poland	Poznan University of Medical Sciences	Mar 2020	0
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	0
Spain	La Paz University Hospital	Jul 2019	19
Spain	Hospital Clinic de Barcelona	Jul 2019	14
Spain	University Hospital 12 de Octubre	Jul 2019	24
Spain	Hospital de Sant Joan de Deu	Oct 2019	8
Spain	Hospital Clinico San Carlos	Sep 2019	8
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	4
Spain	H. Universitario Marqués de Valdecilla	Dec 2019	2
Spain	H. U. Virgen de las Nieves, Granada	Jan 2020	3
Spain	C. U. Universitario de Santiago	Jan 2020	0

Country	Centre	Randomised since	Randomisations
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	1
Switzerland	Zürich University Hospital	Dec 2019	6
Switzerland	Luzerner Kantonsspital	Jan 2020	3
Switzerland	Geneva University Hospital	Feb 2020	0
Turkey	Gazi University Hospital	Jan 2020	4
Turkey	Marmara University Hospital	Jan 2020	4
Turkey	Uludag University Hospital	Jan 2020	0
Turkey	Kanuni Sultan University Hospital	Jan 2020	5
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	5
Total			178

As you can see below, the randomisation rate has decreased in March. We suspect that this is due to the COVID-19 outbreak in Europe since the number of weekly randomisations dropped significantly simultaneous to the European outbreak.



Minutes from Steering Committee Meeting, 17th of March

The Sixth Steering Committee meeting was held through the online platform Zoom at 17th of March. You can find the minutes here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sc-meeting-march.pdf>

Central monitoring report

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

<https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/klinisk-biokemisk-afdeling-for-fagfolk/Documents/analyser/cmr-20-03-2020-for-fagfolk.pdf>

As you can see, completion of data entries is good (98% completion of End-of-monitoring module, 100% completion of follow-up module, 99% completion of blinded follow-up module). Investigators with missing data entries have been contacted and urged to complete data entries.

Thank you for your time,

Best wishes

Gorm and Mathias