

SafeBoosC-III newsletter June 2020

Dear investigators

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

Update to trial documents

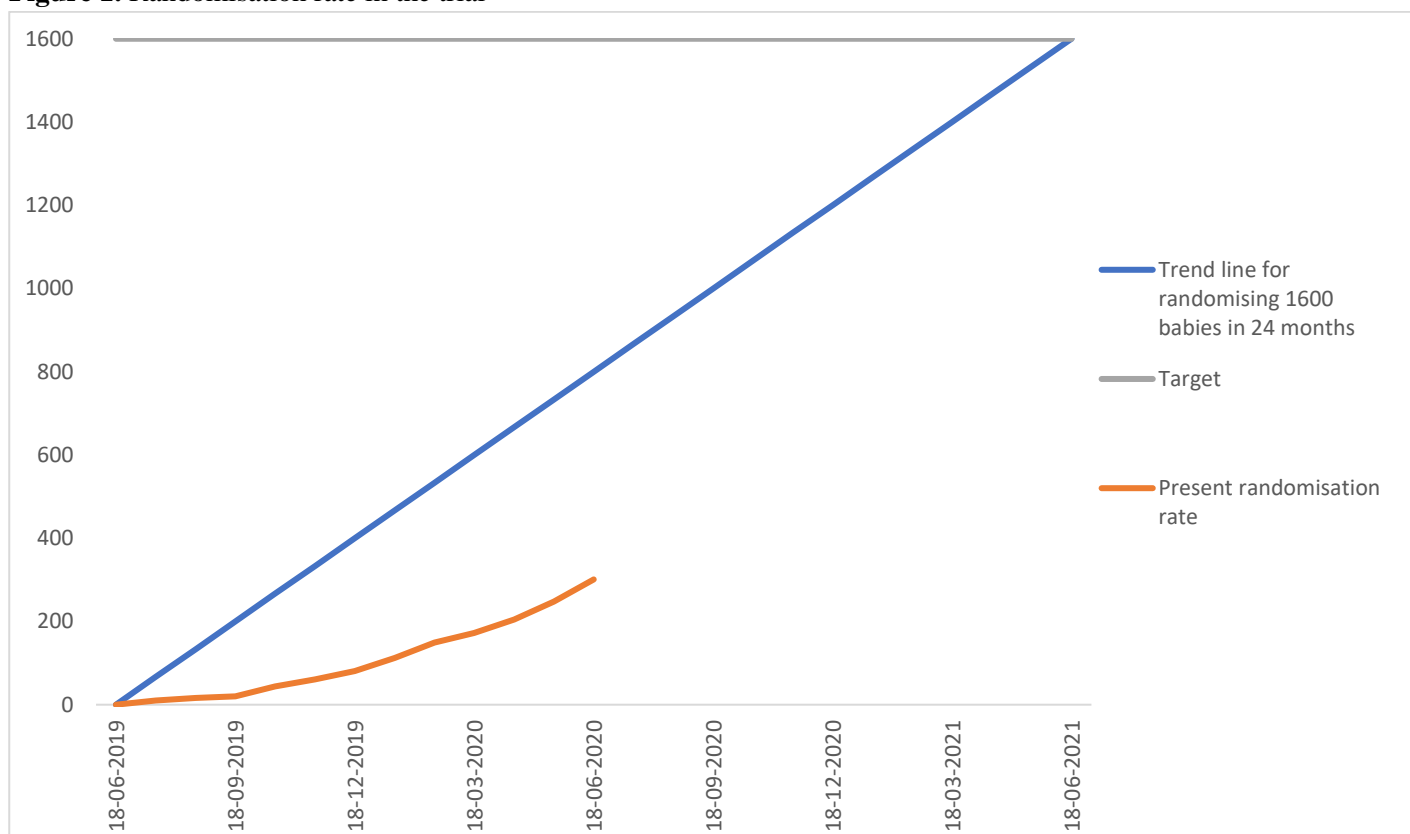
GCP monitoring report: addition of text regarding that signatures on the parental information sheet does not have to be dated before beginning of the intervention if deferred consent is used. Direct link to the updated document:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/gcp-monitoring-report.pdf>

Status on randomisations and trial preparations

As of the 18th of June, a total of 301 babies have been randomised and the rate is now higher than before the COVID-19 outbreak (**figure 1**).

Figure 1. Randomisation rate in the trial



Since we sent out the May issue of the newsletter, an additional six hospitals have been opened for randomisation, which brings the total number of open hospitals up to 46. With an additional 33 hospitals actively preparing for the trial, we are confident that the randomisation rate will increase even more over the

next couple of months. In **table 1** below, you will find an overview of the randomisations in each of the 46 open hospitals.

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

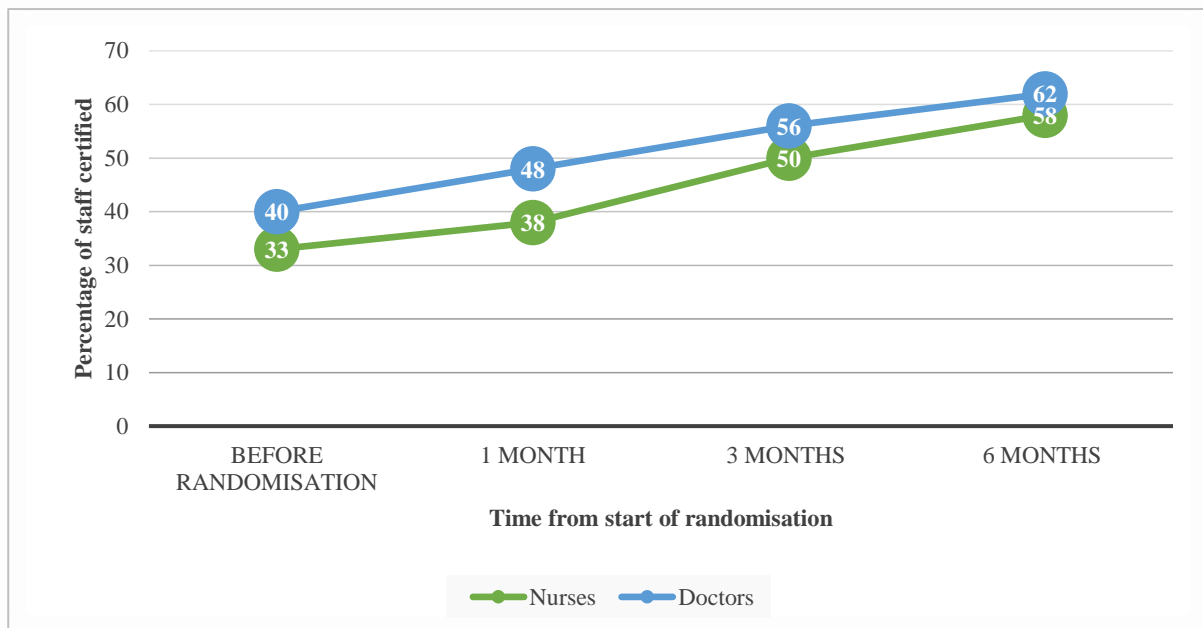
Country	Centre	Randomised since	Randomisations
Austria	University Hospital Graz	June 2020	0
Belgium	UZ Leuven	June 2020	0
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	20
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	7
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	0
China	The People's Hospital of Dehong	May 2020	0
China	Guangxi Maternal and Child Healthcare Hospital, Nanning	May 2020	0
China	Xiamen Children's Hospital	May 2020	0
Denmark	Rigshospitalet	Jun 2019	47
Denmark	Odense University Hospital	Dec 2019	3
Denmark	Aalborg University Hospital	Mar 2020	0
Denmark	Aarhus University Hospital	May 2020	0
Germany	Freiburg University Hospital	June 2020	0
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	11
Greece	University of Patras General Hospital	Jan 2020	5
Greece	Alexandra Univ. Hospital	March 2020	4
Greece	University Hospital of Heraklion	March 2020	2
India	St Johns Medical College Hospital, Bangalore	June 2020	0
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	14
Poland	Medical Center UJASTEK, Krakow	Jan 2020	8
Poland	Poznan University of Medical Sciences	Mar 2020	5
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	2
Poland	Wroclaw Medical University	Apr 2020	0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	6

Country	Centre	Randomised since	Randomisations
Spain	La Paz University Hospital	Jul 2019	26
Spain	Hospital Clinic de Barcelona	Jul 2019	23
Spain	University Hospital 12 de Octubre	Jul 2019	27
Spain	Hospital de Sant Joan de Deu	Oct 2019	11
Spain	Hospital Clinico San Carlos	Sep 2019	11
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	11
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
Spain	Hospital Miguel Servet	Apr 2020	0
Switzerland	Zürich University Hospital	Dec 2019	9
Switzerland	Luzerner Kantonsspital	Jan 2020	9
Switzerland	Geneva University Hospital	May 2020	3
Turkey	Gazi University Hospital	Jan 2020	4
Turkey	Marmara University Hospital	Jan 2020	8
Turkey	Uludag University Hospital	Jan 2020	2
Turkey	Kanuni Sultan University Hospital	Jan 2020	9
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	11
United States	University of Utah	June 2020	0
Total			302

Status on the SafeBoosC-III web-based training and certification program

Currently, over 1000 staff members from 69 departments are enrolled in the SafeBoosC-III web-based training program. The training modules are available in seven languages. We continuously monitor and notify local investigators of certifications rates before start of randomisation and at one, three and six months after start of randomisation. Certification rates vary a great deal between the departments, but the average rate is steadily increasing (**figure 2**).

Figure 2. Certification rates over time. An average of all hospitals opened for randomisation



Investigator survey for the SafeBoosC-III follow-up study

The 3rd of June, Marie Rasmussen sent out an e-mail regarding the preparations for the two-year follow-up study. To minimise extra work for investigators, the follow-up study will rely on assessments that are part of the participating hospitals routine follow-up program. Thus, we need to know which routine assessments that are done during follow-up visits in your hospital.

Therefore, we encourage all investigators to click on the survey link in the e-mail, or use the one below, and answer the questions regarding follow-up on extremely preterm infants in your department:

<https://forms.gle/Z3XhiUGD4rMfMcoF6> (works best in Google Chrome)

Central monitoring report

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

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-19-april-2020.pdf>

Despite a decrease as compared to last month, the data completion rate is still acceptable. It is expected that the completion rate will decrease with increasing randomisations. We will work hard to maintain a high data completion rate, because timely reporting is an important part of the quality of the trial.

We are still working on a method of timely detection of major differences in data among hospitals. Central monitoring of multi-centre randomised trials is an emerging field in its own, and we want to take part in the developments. We expect to announce an approved final data monitoring plan within the next month.

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

Thank you for your time,

Best wishes
Gorm and Mathias