

SafeBoosC-III newsletter September 2020

Dear investigators

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

Important change to the end of monitoring form in OpenClinica

Data entry point E07 “Did cerebral oximetry monitoring stop prematurely?” in the End of monitoring form, have been changed to “If the baby survived until 72 hours of age, was cerebral oximetry monitoring stopped for more than 14 hours during this time period?”.

We made this change to ensure that only babies alive at 72 hours of age and with more than 14 hours of missing NIRS monitoring are registered with a YES. We apologize for the previous unclear phrasing.

Change to the online training certification requirements for neonatologists

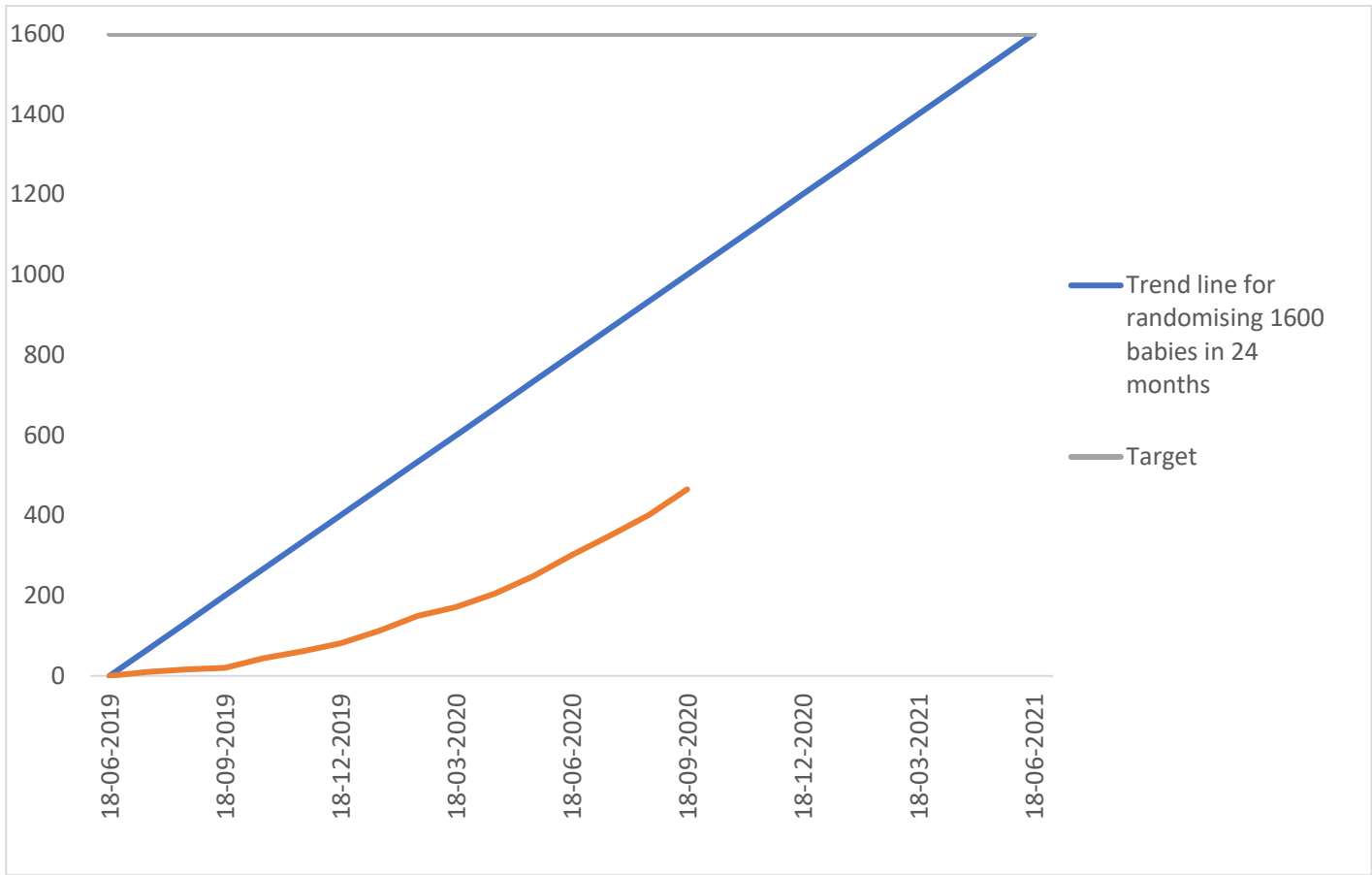
Up until now, neonatologists have had to complete the following modules, in order to obtain certification: 1) introduction, 2) NIRS monitoring, 3) treatment guideline and 4) cranial ultrasound and brain injury. However, in many centres, it is the pediatric radiologists who conduct the ultrasound scans and therefore, it is not meaningful to require that neonatologists complete the ultrasound module in these centres.

Therefore, we have decided that across all centres, neonatologists do not have to complete the module on cranial ultrasound and brain injury to obtain certification. This will also be seen in the up-and-coming certification rates, which we frequently provide you with.

Status on randomisations and trial preparations

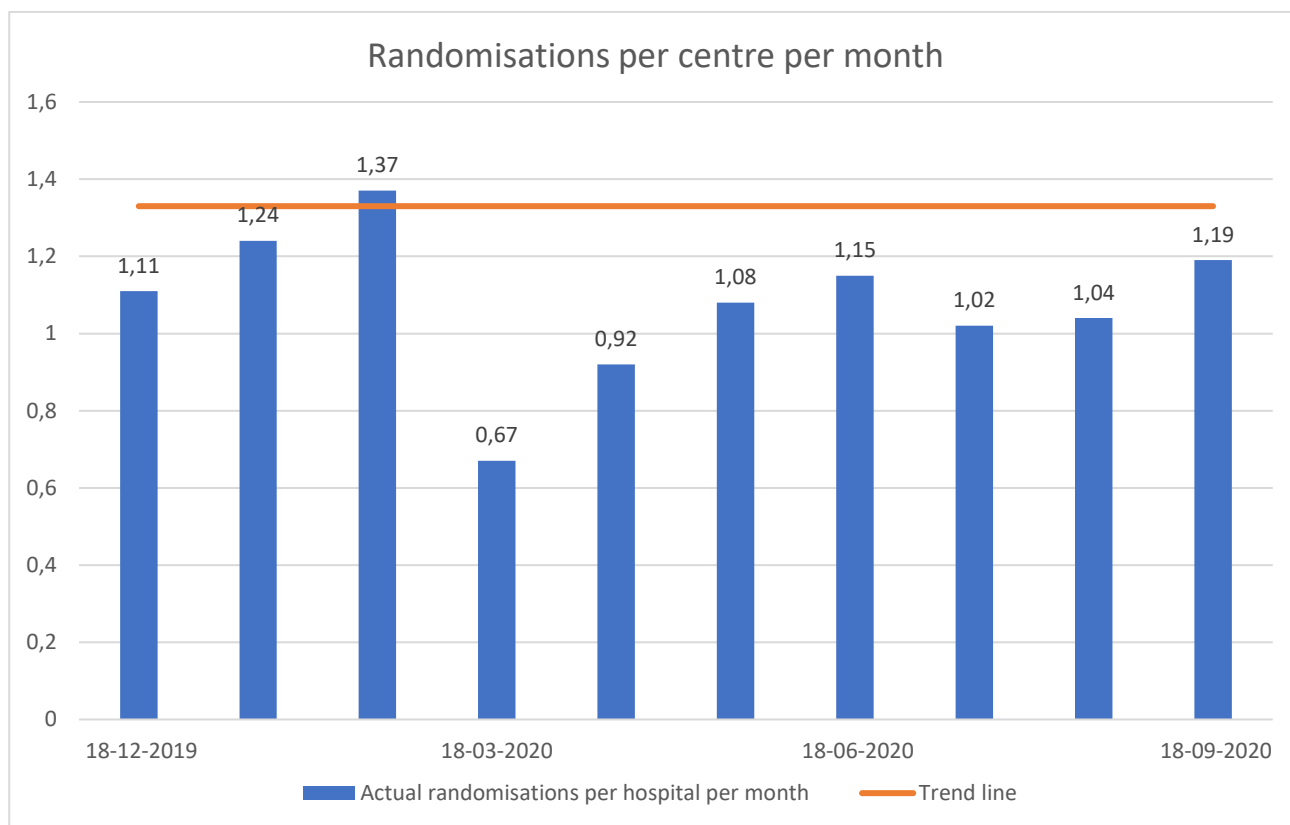
As of the 18th of September, a total of 465 babies have been randomised, which is a great increase compared to previous months (2.02 randomised babies per day compared to 1.65 randomised babies per day in August) (**figure 1**). At the same time, the number of hospitals open for randomisation has increased from 49 to 54, meaning that we have surpassed our initial goal of 50 hospitals open for randomisation. As we expect at least ten more hospitals to open for randomisation within the next months, we are confident that the randomisation rate will increase even more.

Figure 1. Randomisations in the SaeBoosC-III trial



The randomisation rate per hospital has also increased well during the last months, when compared to the last couple of months (**figure 2**). Despite this increase, we are still a bit from the expected hospital randomisation rate of 1.33 babies per month (present rate is 1.19 babies per hospital per month).

Figure 2. Randomisations per hospital per month.



In **table 1** below, you will find an overview of the randomisations in each of the 54 open hospitals up until 18th of September 2020.

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

| Country | Centre | Randomised since | Randomisations |
|----------------|---|------------------|----------------|
| Austria | University Hospital Graz | June 2020 | 2 |
| Belgium | UZ Leuven | June 2020 | 9 |
| Belgium | Liege Rocourt | July 2020 | 0 |
| Belgium | Grand Hospital de Charleroi | July 2020 | 3 |
| Belgium | AZ St. Jan University Hospital Brugge | September 2020 | 0 |
| Belgium | CHU Tivoli | September 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 | 19 |
| China | Hainan Women and Children's Medical Center | Mar 2020 | 0 |

| Country | Centre | Randomised since | Randomisations |
|---------|--|------------------|----------------|
| China | Guangzhou Women and Children's Medical Center | Mar 2020 | 1 |
| China | Longgang District Central Hospital of Shenzhen | May 2020 | 3 |
| China | The People's Hospital of Dehong | May 2020 | 0 |
| China | Guangxi Maternal and Child Healthcare Hospital, Nanning | May 2020 | 1 |
| China | Xiamen Children's Hospital | May 2020 | 0 |
| Denmark | Rigshospitalet | Jun 2019 | 59 |
| Denmark | Odense University Hospital | Dec 2019 | 3 |
| Denmark | Aalborg University Hospital | Mar 2020 | 1 |
| Denmark | Aarhus University Hospital | May 2020 | 3 |
| Germany | Freiburg University Hospital | June 2020 | 3 |
| Greece | Ippokrateion General Hospital of Thessaloniki | Oct 2019 | 18 |
| Greece | University of Patras General Hospital | Jan 2020 | 6 |
| Greece | Alexandra Univ. Hospital | March 2020 | 8 |
| Greece | University Hospital of Heraklion | March 2020 | 4 |
| India | St Johns Medical College Hospital, Bangalore | June 2020 | 1 |
| 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 | 11 |
| Poland | Poznan University of Medical Sciences | Mar 2020 | 12 |
| Poland | Specialist Hospital No. 2 in Bytow | Feb 2020 | 3 |
| Poland | Wroclaw Medical University | Apr 2020 | 0 |
| Poland | Jan Biziel University Hospital | Pending | 0 |
| Spain | H. Univ. Juan XXIII de Tarragona Hospital | Feb 2020 | 9 |
| Spain | La Paz University Hospital | Jul 2019 | 34 |
| Spain | Hospital Clinic de Barcelona | Jul 2019 | 30 |
| Spain | University Hospital 12 de Octubre | Jul 2019 | 30 |
| Spain | Hospital de Sant Joan de Deu | Oct 2019 | 19 |
| Spain | Hospital Clinico San Carlos | Sep 2019 | 14 |
| Spain | Hospital Universitarie Puerta del Mar | Oct 2019 | 11 |
| Spain | H. Universitario Marqués de Valdecilla | Dec 2019 | 9 |
| Spain | H. U. Virgen de las Nieves, Granada | Jan 2020 | 5 |
| Spain | C. U. Universitario de Santiago | Jan 2020 | 0 |
| Spain | Hospital Miguel Servet | Apr 2020 | 0 |

| Country | Centre | Randomised since | Randomisations |
|---------------|---|------------------|----------------|
| Switzerland | Zürich University Hospital | Dec 2019 | 17 |
| Switzerland | Luzerner Kantonsspital | Jan 2020 | 15 |
| Switzerland | Geneva University Hospital | May 2020 | 4 |
| Switzerland | Lausanne University Hospital | September 2020 | 0 |
| Turkey | Gazi University Hospital | Jan 2020 | 5 |
| Turkey | Marmara University Hospital | Jan 2020 | 12 |
| Turkey | Uludag University Hospital | Jan 2020 | 12 |
| Turkey | Kanuni Sultan University Hospital | Jan 2020 | 11 |
| Turkey | Bilkent Integrated Health Care Campus | Jan 2020 | 21 |
| United States | University of Utah, Division of Neonatology | June 2020 | 2 |
| United states | Loma Linda University Hospital | September 2020 | 2 |
| Total | | | 465 |

Data completion monitoring report

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

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-18-september-2020.pdf>

For the end of monitoring and follow-up form, completion of data entries is still good with 94% and 98% completion respectively. Completion of the blinded follow-up form is almost unchanged since last month (84% compared to 83% last month) and thus, are still lacking a bit behind the other data entry forms.

As of this month, the setup of the SAR form has also changed, meaning that investigators most actively complete the forms even if no SARs are registered. Therefore, we have also started to monitor data completion of the SAR forms. As this change was recently implemented, it is not unexpected that only 56% of the SAR forms are completed. We hope this to increase until next month.

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

In the link below you will find the first central monitoring report regarding data quality.

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

A monitoring report regarding 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>

Minutes from SafeBoosC steering committee meeting

The ninth steering committee meeting were held on 21st of September through the online Zoom platform.

Minutes from the meeting can be found here:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sc-meeting-september-2020.pdf>

Thank you for your time,

Best wishes

Gorm and Mathias