

SafeBoosC III newsletter, October 2019

Dear investigators

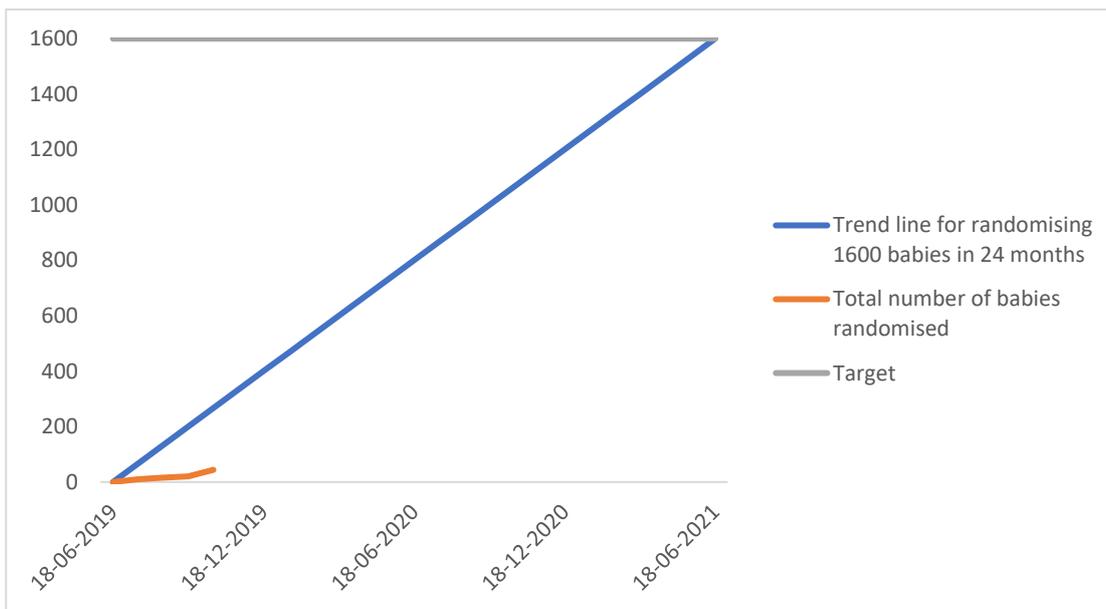
Welcome to the October version of the SafeBoosC III newsletter.

Status on randomisations and trial preparations.

As of 29st of October, we have opened for randomisation in 10 sites. Below you will find an overview of the randomisation in each centre.

Country	Centre	Opened for randomisation	Randomisation
Czech Republic	The Institute for the Care of Mother and Child	9-sept 2019	10
Denmark	Rigshospitalet	18-jun 2019	16
Greece	Ippokrateion General Hospital of Thessaloniki	3-oct 2019	0
Spain	La Paz University Hospital	18-jul 2019	7
Spain	Hospital Clinic de Barcelona	9-jul 2019	5
Spain	University Hospital 12 de Octubre	8-jul 2019	8
Spain	Hospital de Sant Joan de Deu	2-oct 2019	1
Spain	Hospital Clinico San Carlos	30-sep 2019	0
Spain	Hospital Universitarie Puerta del Mar	21-oct 2019	0
Switzerland	Zürich University Hospital	23-oct 2019	0
Total			47

The randomisation rate has also increased since jENS in September. However, if we ought to reach our aim of randomising 1600 babies within 24 months (June 2021), we need to increase the pace even more.



An additional 39 sites have obtained IRB/REB approval and we expect that 20 sites are randomising before the end of this year.

2nd Investigator meeting in Copenhagen

Please remember that deadline for registration is 1st of December. The meeting will be held at the same location as in January, AC Hotel Bella Sky, from 23rd to 24th of January 2020.

Please see the invitation for more details: <https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/invitation-for-2nd-investigator-meeting.pdf>

Funding from Svend Andersen Foundation

As of early October, we have been granted 1,000,000 dkk (approx 135,000 euro) by the Svend Andersen Foundation. The money will be used to cover the second year of Copenhagen Trial Units work, as well as location and hospitality during the next three investigator meetings. We will continue to apply for money to pay for Copenhagen Trial Units during year three and four, and one extra year (fourth year) salary to Mathias, so that he can continue working full-time on the project, until the main results have been published.

First SafeBoosC III publication

The manuscript on the statistical analysis plan have been accepted for publication in Trials Journal and is currently in press. We will upload the paper to www.safeboosc.eu when it becomes available.

Central data monitoring plan

We have developed a central data monitoring plan, which will be discussed at the next steering committee meeting 18th of November. Central data monitoring will be done by us, in collaboration with Copenhagen Trial Unit, and will consist of monitoring of all data entries into the electronic case report form by local hospitals. The purpose of central monitoring is to 1) detect, report and complete any missing data and 2) find systematic deviations in data entries. We expect to start monitoring end of November. Missing data entries as well as systematic data deviations will be reported to the relevant principal investigator.

Technical problems with web-based training

Some investigators have experienced that some letters have been missing from the web-based training modules, while using Internet Explorer and Safari. We have tested this ourselves and experienced similar issues. Therefore, we strongly recommend the use of Google Chrome when partaking the modules.

We also found an error in the logging of completed modules, meaning that some investigators have received incorrect certification rates. However, the technical error has been fixed and relevant investigators and staff have been contacted to clarify certification rates.

We apologize for these inconveniences.

Updates to trial documents

- Report template for monitoring visits: <https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/sop-classification-of-brain-injury-301019.pdf>

Textual change to point 3.0, so that the headline of 3.0 is now only “Delegation and Training log”.

- SOP: diagnosis and classification of brain injury:
<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/gcp-monitoring-report-281019.pdf>
Minor textual change, “these images” has been changed to “the classification”.

Best wishes,
Gorm and Mathias