

SafeBoosC-III newsletter May 2020

Dear investigators

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

24/7 emergency phone number for randomisation issues

We have decided to provide a 24-hour service for urgent randomisation issues. Therefore, in case you experience any such issues, you are welcome to contact Mathias Lühr Hansen (+45 27142144) or Gorm Greisen (+45 40460747). However, these are our private phone numbers and therefore, the call is not toll-free.

Please also remember that these phone numbers are only for urgent randomisation issues – other trial enquires should go through e-mail as usual.

The phone numbers has also been added to the SOP: enrolment and randomisation:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/sop-enrollment-and-randomisation.pdf>

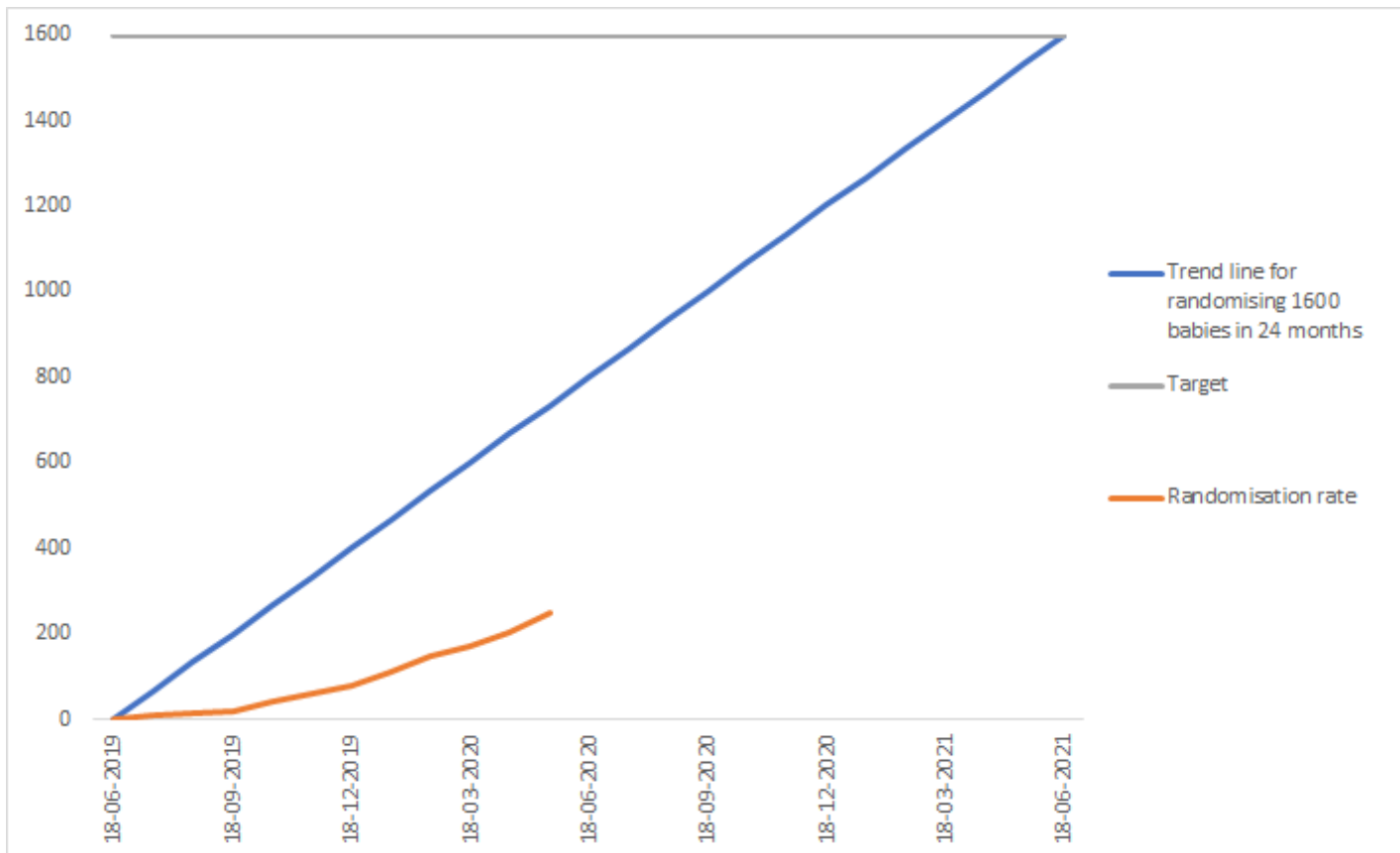
Status on randomisations and trial preparations

Despite a significant increase in the number of hospitals open for randomisation during the last couple of months, the randomisation rate has not increased as compared to before the COVID-19 epidemic – although it is slightly better than the last two months. During the latest steering group meeting, this issue was discussed, and several national coordinators reported that the rate of preterm births had decreased in their respective hospitals since the COVID-19 epidemic begun. We do not know if this is a general trend or simply a coincidence in the steering group.

As of 19th of May, we have opened for randomisation in 40 centres and 248 babies have been randomised. Furthermore, 40 additional centres are actively preparing for the trial, meaning that they have completed at least one of the trial preparation tasks. Below you will find an overview of randomisations in each of the 36 open centres.

Country	Centre	Randomised since	Randomisations
Czech Republic	The Institute for the Care of Mother and Child	Sep 2019	15
China	Children's Hospital of Zhejiang, Hangzhou	Jan 2020	0
China	Children's Hospital of Fudan University, Shanghai	Jan 2020	4
China	Hainan Women and Children's Medical Center	Mar 2020	0
China	Guangzhou Women and Children's Medical Center	Mar 2020	0
China	Longgang District Central Hospital of Shenzhen	May 2020	0

Country	Centre	Randomised since	Randomisations
China	The People's Hospital of Dehong	May 2020	0
Denmark	Rigshospitalet	Jun 2019	44
Denmark	Odense University Hospital	Dec 2019	1
Denmark	Aalborg University Hospital	Mar 2020	0
Denmark	Aarhus University Hospital	May 2020	0
Greece	Ippokrateion General Hospital of Thessaloniki	Oct 2019	9
Greece	University of Patras General Hospital	Jan 2020	2
Greece	Alexandra Univ. Hospital	March 2020	3
Greece	University Hospital of Heraklion	March 2020	0
Italy	Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico, Milano	Nov 2019	12
Poland	Medical Center UJASTEK, Krakow	Jan 2020	6
Poland	Poznan University of Medical Sciences	Mar 2020	3
Poland	Specialist Hospital No. 2 in Bytow	Feb 2020	0
Poland	Wroclaw Medical University	Apr 2020	0
Spain	H. Univ. Juan XXIII de Tarragona Hospital	Feb 2020	5
Spain	La Paz University Hospital	Jul 2019	23
Spain	Hospital Clinic de Barcelona	Jul 2019	20
Spain	University Hospital 12 de Octubre	Jul 2019	25
Spain	Hospital de Sant Joan de Deu	Oct 2019	11
Spain	Hospital Clinico San Carlos	Sep 2019	10
Spain	Hospital Universitarie Puerta del Mar	Oct 2019	9
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	7
Switzerland	Luzerner Kantonsspital	Jan 2020	8
Switzerland	Geneva University Hospital	May 2020	0
Turkey	Gazi University Hospital	Jan 2020	4
Turkey	Marmara University Hospital	Jan 2020	7
Turkey	Uludag University Hospital	Jan 2020	1
Turkey	Kanuni Sultan University Hospital	Jan 2020	7
Turkey	Bilkent Integrated Health Care Campus	Jan 2020	7
Total			248



Central monitoring report

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

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/data-completion-report-19-05-2020.pdf>

Completion of data entries is still good and has even increased a bit since last month (97% versus 97% completion of end of monitoring module, 98% versus 97% completion of follow-up module, and 93% versus 88% completion of blinded follow-up module), despite that more babies have reached the age for data entry. We will work hard to maintain this, because timely reporting is an important part of the quality of the trial.

Furthermore, we work on a method of timely detection of major differences 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.

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

Minutes from steering group meeting, 18th of May 2020

The seventh steering group meeting was held 18th of May through the online platform Zoom. You can find the minutes of the meeting below:

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

Status on the SafeBoosC III follow-up study

We expect to have a draft study synopsis in the beginning of June which, together with a formal invitation and a questionnaire on local follow-up programs, will be sent out to all principal investigators. The purpose of the questionnaire is to chart the routine follow-up programs that are used in our hospitals. We need this to design a feasible follow-up study.

General Movement Assessments ancillary study approved

The GMA ancillary study protocol has been formally approved by the steering group and the protocol can now be found on the webpage:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/general-movement-meta-analysis.pdf>

We encourage all investigators to read the protocol. If you are interested to participate, please contact Gerhard Pichler from Graz University Hospital at Gerhard.pichler@medunigraz.at.

Paper on the piloting of the NIRS online training module is published

The paper with the title “Pilot test of an online training module on near-infrared spectroscopy monitoring for the randomised clinical trial SafeBoosC-III” has been published in Trials journal. This is the third SafeBoosC-III publication. As with previous publications, it can be found on the webpage:

<https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/for-professionals/pilot-test-of-online-training-module-nism-for-randomised-clinical-trial-safeboosc-iii.pdf>

Thank you for your time,

Best wishes

Gorm and Mathias