

SafeBoosC-IIIv Newsletter

**Randomisations:
146**

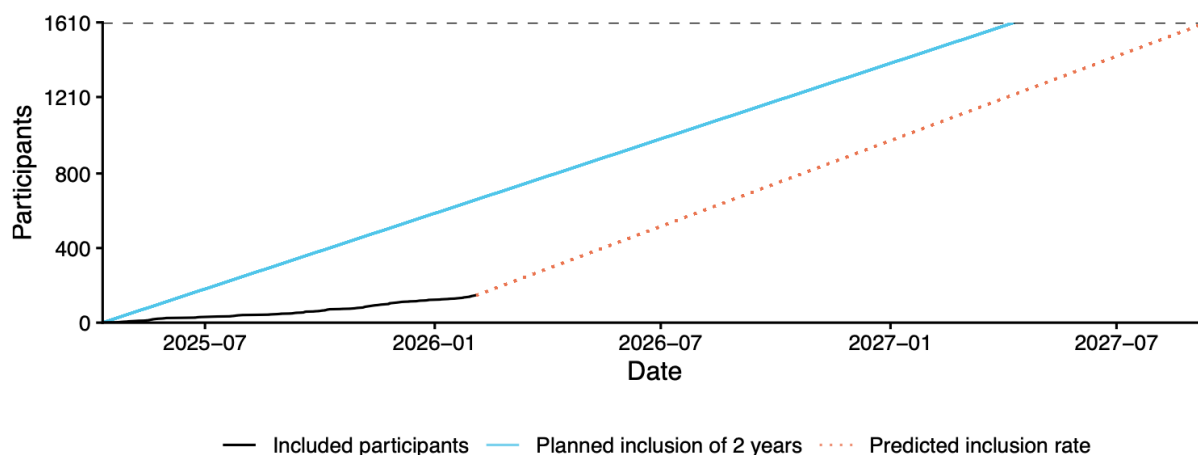
Dear Investigators,

This is the SafeBoosC-IIIv newsletter, which we will send out regularly and publish on the website (safeboosc.eu) to keep you continuously updated. We will send the newsletter to all Principal Investigators and National Coordinators. Please let us know if you wish to add an email address to the list.

We are pleased to announce that we have currently randomised 146 participants. In January, another Spanish centre began randomisation: Hospital Universitario Virgen Las Nieves in Granada led by Laura Serrano Lopez. In addition, another Spanish centre completed all steps required for randomisation. We have opened for randomisation in Spain, Romania, Austria, Greece, and India.

We expect a number of new centres to begin randomisation in spring 2026. Please see the current rate of inclusion below:

The trial has been running for 0.8 years (2025-04-11). Until now 146 participants have been included. Based on the last 10 participants there is an average of 0.4 days between each inclusion. Thus, inclusion must be continued for another approx. 1.6 years (2027-09-11) to reach the required sample size (n=1610).



Overview of the enrollment rate.

Substudy meeting

The next substudy meeting is scheduled on **15 April 16:30-17:30 CEST**. You will receive a calendar invite in a separate email. We hope to see more substudy proposals utilising the SafeBoosC-IIIv data. Please contact Caroline Kamp if you or your colleagues have an idea for a substudy. We would be happy to assist you in developing the substudy.

Publications

The protocol has been peer reviewed at *Trials*, and we have now received the reviewers' comments. We will share the updated manuscript with the author group soon.

Ethics approval

The SafeBoosC-IIIv trial has received ethics approval in Denmark and is not classified as a medical device trial. Please find attached a translated version of the letter sent to the Danish ethics committee, in which we argued that the trial should be approved as research in an emergency setting (allowing deferred consent) and not be classified as a medical device trial. You are welcome to use this documentation for your local ethics submissions.

Screening

We have received some questions regarding the screening of potential participants. In general, all participants considered for inclusion in the trial by the investigators should be included in the screening log. Please find the screening and randomisation standard operating procedure attached.

Principal Investigator status

In total, 16 centres have completed all the required preparatory steps and are ready for randomisation. Overall, we are in contact with almost 80 centres from 22 countries. Please see the attached list for the latest progress from all centres and let us know if you have any updates.

Please contact us if you have any questions about the process. We are also available for online meetings to support you in the process.

Best wishes,
Caroline, Johanne, and Janus

Country	Centre	Ethics approval	Signed collaboration agreement	Approved blinding procedure	Local monitoring initiation visit	Delegation log	Randomisations
Argentina	Hospital Universitario Austral, Pilar						
Australia	Grace Centre for Newborn Intensive Care in The Children's Hospital at Westmead, Sydney						
Austria	University Hospital Graz, Graz						1
Austria	Department of Pediatrics II, Medical University of Innsbruck, Innsbruck						7
Belgium	University Hospital Leuven, Leuven						
Brazil	Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande d						
Brazil	Hospital São Paulo / Escola Paulista de Medicina, São Paulo						
Brazil	Hosp das Clínicas /Faculdade de Med de Botucatu, Botucatu						
Brazil	Centro de Atenção a Saúde da Mulher / UNICAMP, Campinas						
Brazil	Hospital das Clínicas / UFMG, Belo Horizonte						
Brazil	Hospital das Clínicas / UFU, Uberlândia						
Brazil	Hospital Universitário / UFMA, São Luís						
Brazil	Maternidade Carmela Dutra, Florianópolis						
Brazil	Mat. de Referencia Prof Jose Maria de Magalhães, Salvador						
Canada	Department of Pediatrics, University of Alberta, Edmonton						
Chile	Hospital Clínico de la Universidad Católica						
China	Children's Hospital of Fudan University						
Czech Republic	University Hospital Motol, Prague						
Denmark	Copenhagen University Hospital, Copenhagen						
Denmark	Aalborg University Hospital, Aalborg						
Germany	Medical Center, University of Freiburg, Freiburg						
Greece	University of Patras, General Hospital, Rio						6
Greece	Hippokrateion General Hospital of Thessaloniki, Thessaloniki						7
Greece	Alexandra University and State Maternity Hospital, Athens						3
Greece	University Hospital of Heraklion, Heraklion						6
Greece	Papageorgiou General Hospital of Thessaloniki, Thessaloniki						
Greece	NICU Ioannina University Hospital, Northwest Greece						
India	St John's Medical College Hospital, Bengaluru, Karnataka						14
India	Goa Medical College						
India	Bhuvaneshwar, Orissa						
India	Bangalore Baptist Hospital, Bengaluru						
Ireland	INFANT Research Centre, University College Cork, Cork						
Italy	Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan						
Poland	Poznan University of Medical Sciences, Poznan						
Poland	Górnośląskie Centrum Zdrowia Dziecka, Katowice						
Poland	Centrum Medyczne Ujastek, Kraków						
Poland	Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego, Warszawa						
Poland	Centralny Szpital Kliniczny Uniwersytetu Medycznego, Łódź						
Poland	Instytut Matki i Dziecka, Warszawa						
Poland	Instytut Centrum Zdrowia Matki Polki, Łódź						
Romania	Clinical County Hospital Sibiu						
Romania	Clinical County Emergency Hospital Tg. Mureș						
Romania	The National Institute for Mother and Child Care Alessandrescu-Rusescu, P						23
Romania	Clinical County Emergency Hospital Constanța						
Romania	Maternity Hospital Cuza-Vodă Iași						
Romania	Life Memorial Hospital Bucharest						
Spain	La Paz University Hospital, Madrid						36
Spain	Complejo Hospitalario san Carlos						
Spain	Hospital Universitario 12 de Octubre						31
Spain	Hospital Universitario Quironsalud Madrid						
Spain	Hospital Universitario Puerta del Mar						8
Spain	Hospital Universitario Virgen Las Nieves, Granada						1
Spain	Hospital Miguel Servet						
Spain	Department of Neonatology, Hospital Clínic Barcelona, BCNatal-Barcelona Center for Maternal-Fetal and N						3
Spain	Hospital Marques de Valdecilla						
Spain	Hospital De Sant Joan De Deu, Barcelona						
Spain	Hospital Universitario Donostia IIS Biogipuzkoa						
Switzerland	Children's University Hospital of Zürich, Zürich						
Switzerland	Children's Hospital Lucerne, Lucerne						
Switzerland	University Hospital Center of Lausanne						
Türkiye	Basakşehir Cam and Sakura City Hospital, Dept of Neonatology, İstanbul						
Türkiye	Marmara University, Pendik Teaching and Research Hospital, Dept of Neonatology, İstanbul						
Türkiye	Ankara Bilkent City Hospital, Dept of Neonatology, Ankara						
Türkiye	Bursa Uludağ University, Dept of Neonatology						
Türkiye	Istanbul Training and Research Hospital, Dept of Neonatology, İstanbul						
United Kingdom							
United States	UT Southwestern Medical Center, Dallas						
United States	Loma Linda University Children's Hospital, Los Angeles						
United States	University of Florida						
Zambia	Women and Newborn Hospital, University Teaching Hospitals, Lusaka						

Completed steps
Draft received - awaiting final version