

SafeBoosC-IIIv Newsletter

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 would like to add an email address to the list.

We are pleased to inform you that we have received interest from countries across six continents. We are currently in contact with more than 50 centres.

Central status

We received a conditional approval of the Danish Research Ethics Committee. We resubmitted the protocol with minor revisions, and we expect a response in December. We are currently working on the final central steps, and we expect to be ready for randomisation by February 2025. We are continuously updating the website (safeboosc.eu) with standard operating procedures, Steering Committee meeting minutes, and other relevant information.

Principal Investigator status

We have contacted all centres with information about local preparation for the trial. Please see the list of progress for all centres below.

Substudies

All investigators are allowed to plan and conduct substudies and subsequent publications based on SafeBoosC-IIIv trial data. Substudies must be approved by the Steering Committee, and we have therefore planned a substudy meeting on 5 February 2025 at 20:30 CET where intended substudies will be presented. The attached standard operating procedure includes more information about the process. Please let us know if you are considering or planning a substudy, so we can support you in this process.

Please do not hesitate to reach out to us if you have any questions or updates from your centre.

Thank you and best wishes,
Caroline, Johanne and Janus

Country	Centre	Signed collaboration agreement	Approved blinding procedure	Ethics approval	GCP initiation visit	Delegation log	Start of randomisation
Argentina	Hospital Universitario Austral, Pilar						
Argentina	Hospital de Pediatría Garrahan, CABA						
Argentina	Hospital de Niños Dr. Ricardo Gutiérrez, CABA						
Argentina	Hospital Italiano de Buenos Aires, CABA						
Austria	University Hospital Graz, Graz						
Austria	Medical University of Innsbruck						
Belgium	University Hospital Leuven, Leuven						
Brazil	Universidade Federal do Rio Grande do Sul, Porto Alegre						
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						
France							
Germany	Medical Center, University of Freiburg, Freiburg						
Greece	University of Patras, General Hospital						
Greece	Ippokrateion General Hospital of Thessaloniki, Thessaloniki						
Greece	"Alexandra" University and State Maternity Hospital, Athens						
Greece	University Hospital of Heraklion, Heraklion						
Greece	Papageorgiou General Hospital of Thessaloniki, Thessaloniki						
India	St John's Medical College Hospital, Karnataka						
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						
Norway	Oslo University Hospital, Oslo						
Poland	Poznan University of Medical Sciences, Poznan						
Portugal	Unidade Local de Saúde São José						
Portugal	Unidade Local de Saúde Santa Maria, Hospital de Santa Maria						
Romania	Clinical County Hospital Sibiu						
Romania	Clinical County Emergency Hospital Tg. Mures						
Romania	The National Institute for Mother and Child Care Rusescu-Polizu Bucuresti						
Romania	Clinical County Emergency Hospital Constanța						
Romania	Maternity Hospital Cuza-Vodă Iași						
Spain	La Paz University Hospital, Madrid						
Spain	Complejo Hospitalario san Carlos						
Spain	Hospital Universitario 12 De Octubre						
Spain	Hospital Universitario Quironsalud Madrid						
Spain	Hospital Universitario Puerta Del Mar						
Spain	Hospital Universitario Virgen Las Nieves						
Spain	Hospital Miguel Servet						
Spain	Hospital Casa De Maternitat (Hospital clinic)						
Spain	Hospital De Sant Joan De Deu (Barcelona)						
Spain	C. H. Universitario De Santiago (CHUS)						
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						
Turkey	Kanuni Sultan Süleyman Training and Research Hospital, Istanbul						
United States	UT Southwestern Medical Center, Dallas						
United States	Loma Linda University Children's Hospital, Los Angeles						
Uruguay	Centro Hospitalario Pereira Rossell, Montevideo						
Zambia	Women and Newborn Hospital, University Teaching Hospitals, Lusaka						
Zambia	Nchanga South Hospital						

Completed steps