



SafeBoosC newsletter Dec 2023

Dear investigators

Welcome to the December 2023 issue of the SafeBoosC newsletter.

SafeBoosC-IIIv

Copenhagen Trial Unit has received a grant of 540.000 euros to cover the central costs for IIIv, including trial management, data management, developing of data systems, conducting statistical analyse for a trial with a 90-day primary outcome. The proposed primary outcome is hospital free days within 90 days from randomisation. In total, 1610 participants must be randomised to achieve sufficient statistical power to demonstrate a 5% relative risk reduction in mortality and a 3-day increase in hospital free days. CTU will continue to seek funds to execute the already published protocol, which includes a 2 year outcome. The hope is to start randomisation at the end of 2024. Please reach out to us if you are interested in participating.

SafeBoosC-III follow-up

So far, 48 of 65 sites with eligible children are open for follow-up and 45 have entered data in OpenClinica. In total, 11 sites who have eligible children have not yet started the follow up and 11 sites have been excluded/withdrawn. A total of 1003 eligible infants have reached two years of corrected age. Of these, 664 (66%) infants have completed data entries in OpenClinica so far. In total, 580 (58%) participants/families have completed the parental questionnaire. For the participants having reached 30 months of corrected age, 79% have enough data for the primary outcome. We are experiencing a bit of a decline in data completions due to many sites have not started following up participants yet. This was discussed at the recent Steering Committee meeting where the decision was made to exclude the Chinese centers and the rest of the national coordinators where encouraged to push the centers falling behind. For an overview of data completion, please see figure 1. For an overview of each sites data completion see table 1.

Figure 1: Overall data completion in the SafeBoosC-III follow up study

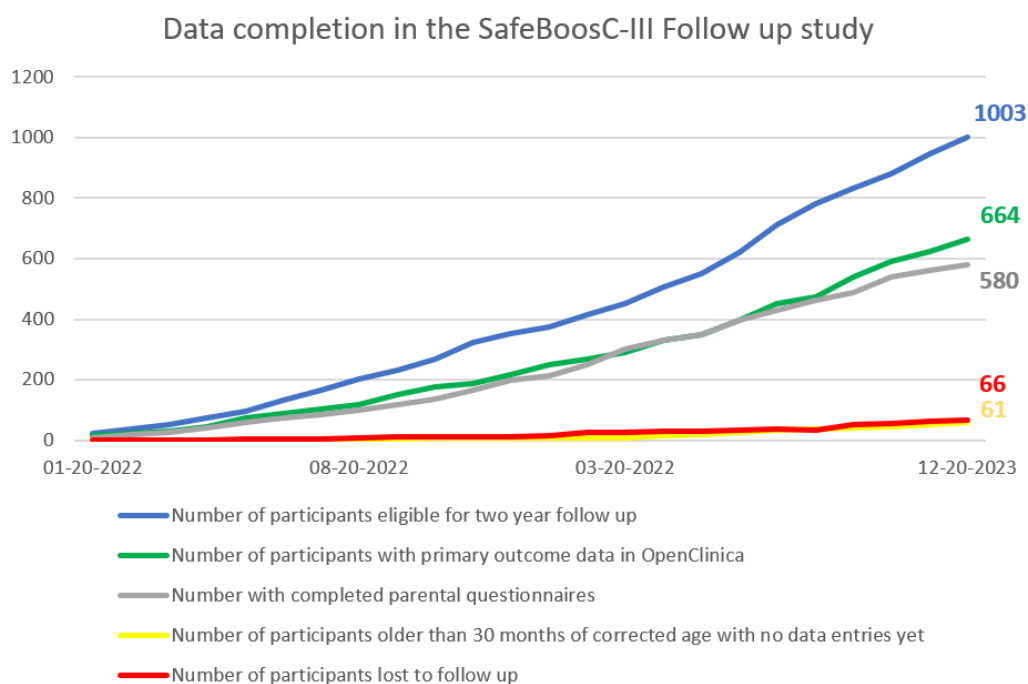




Table 1: Open sites, number of eligible participants for two year follow up and data completion for each site up until the 30th of Dec 2023. Sites highlighted in green indicate that all three tasks (ethics approval, blinding procedure approval and appointment of blinded assessor) have been completed in order to start the follow up study.

Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Austria	University Hospital Graz	13	10	7
Belgium	UZ Leuven	26	24	19
Belgium	Liege Rocourt	18	16	10
Belgium	Grand Hospital de Charleroi	12	5	6
Belgium	AZ St. Jan University Hospital Brugge	10	10	8
Belgium	CHU Tivoli	13 (missing blinded assessor)		
Czech Republic	The Institute for the Care of Mother and Child	54	42	26
Czech Republic	Motol University Hospital	6	0	0
China	Children's Hospital of Zhejiang, Hangzhou	Excluded		
China	Children's Hospital of Fudan University, Shanghai	Excluded		
China	Hainan Women and Children's Medical Center	Excluded		
China	Guangzhou Women and Children's Medical Center	No data		
China	Longgang District Central Hospital of Shenzhen	Excluded		
China	The People's Hospital of Dehong	Withdrawn from SafeBoosC-III trial		
China	Guangxi Maternal and Child	Excluded		



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
	Healthcare Hospital, Nanning			
China	Xiamen Children's Hospital	Excluded		
Denmark	Rigshospitalet	78	66	37
Denmark	Odense University Hospital	7	3	3
Denmark	Aalborg University Hospital	15	8	8
Denmark	Aarhus University Hospital	16	12	9
Germany	Freiburg University Hospital	13	5	5
Greece	Ippokrateion General Hospital of Thessaloniki	20	19	8
Greece	University of Patras General Hospital	6	6	2
Greece	Alexandra Univ. Hospital	13	12	11
Greece	University Hospital of Heraklion	8	7	6
India	St Johns Medical College Hospital, Bangalore	4	4	3
Ireland	University Hospital Cork	15	0	0
Ireland	Rotunda Hospital Dublin	4 (missing all three prep tasks)		
Ireland	NMH Holles St	4	1	0
Ireland	Coombe Univ. Hospital	4 (missing all three prep tasks)		
Italy	Fondazione IRCCS Cà Granda Ospedale, Milano	31	30	26
Italy	Presidio Ospedaliero S. Anna, Turin	7	1	1
Italy	Ospedale Fillipo del Ponte, Varese	withdrawn		



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Italy	Fondazione Policlinico Univ. A. Gemelli, Roma	4 (missing all three prep tasks)		
Norway	Oslo University Hospital	20		
Poland	Medical Center UJASTEK, Krakow	30	Clinical data not available	24
Poland	Szpital Uniwersytecki, Kraków	6 (missing blinding procedure and assessor)		
Poland	Warsaw University of Medical Sciences	9	9	9
Poland	Poznan University of Medical Sciences	28	Clinical data not available	24
Poland	Specialist Hospital No. 2 in Bytom	6	0	0
Poland	Wroclaw Medical University	3 (missing blinding procedure and assessor)		
Poland	Jan Biziel University Hospital	1 (missing blinding procedure and assessor)		
Poland	Centre of Medical Postgraduate Education, Warsaw	2 (missing blinding procedure and assessor)		
Spain	H. Univ. Juan XXIII de Tarragona Hospital	excluded		
Spain	La Paz University Hospital	58	51	46
Spain	Hospital Clinic de Barcelona	46	41	28
Spain	University Hospital 12 de Octubre	50	48	19
Spain	Hospital de Sant Joan de Deu	23	17	14
Spain	Hospital Clinico San Carlos	26	23	20
Spain	Hospital Universitarie Puerta del Mar	12	10	9



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
Spain	H. Universitario Marqués de Valdecilla	13	11	8
Spain	H. U. Virgen de las Nieves, Granada	excluded		
Spain	Hospital Miguel Servet	1 (missing all three prep tasks)		
Spain	Hospital de Cruces	2 (missing all three prep tasks)		
Switzerland	Zürich University Hospital	33	21	25
Switzerland	Luzerner Kantonsspital	33	31	17
Switzerland	Geneva University Hospital	9	9	7
Switzerland	Lausanne University Hospital	17	13	13
Turkey	Gazi University Hospital	7	5	6
Turkey	Marmara University Hospital	22	21	17
Turkey	Uludag University Hospital	21	18	15
Turkey	Kanuni Sultan University Hospital	8	8	6
Turkey	Bilkent Integrated Health Care Campus	19	11	8
Turkey	Basaksehir City Hospital	10	10	5
United Kingdom	Royal Hospital for Children, Glasgow	12	0	0
United Kingdom	NHS Lanarkshire Hospital, Wishaw	4 (waiting for last paperwork)		
United States	University of Utah, Division of Neonatology	19	12	13
United States	Loma Linda University Hospital	22	7	0
United States	UT Southwestern Medical Center, Dallas	3	1	0



Country	Site	Participants eligible for two year follow up	Completed data entries in OpenClinica	Completed parental questionnaires
United States	Washington Univ. Hospital	6	3	1

Thank you for your time,

Marie and Gorm