SafeBoosC III Data completion report

07th of March 2022

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 7th of March 2022. Recruitment was reached on the 16th of December. A total of 1601 participants have been randomised. The data has been analysed and reported according to the SafeBoosC III Central monitoring plan (see www.safeboosc.eu under "Good Clinical Practice").

Direct link to the Central monitoring plan: https://www.rigshospitalet.dk/english/departments/juliane-marie-centre/department-of-neonatology/research/SafeboosC-III/Documents/central-monitoring-plan.pdf

Completion of data entries

Below you will find an overview of the completion of data entries across all centres.

Note that completion calculations are based on babies that have reached 3 days of life for end-of-monitoring completion and serious adverse reactions completion, and 36 weeks of postmenstrual age (PMA) for Follow-up and Blinded follow-up completion. The completion calculations are also based on babies eligible for data entry meaning that babies were consent has been declined/withdrawn are not included.

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
AT01 Univ. Hospital Graz	**21**	**100%**	**100%**	**100%**	**100%**
BE01 Univ. Hospital Leuven	**32**	**100%**	**100%**	**100%**	**100%**

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
BE02 AZ St. Jain Univ. Hosp. Bruges	14	100%	100%	100%	100%
BE03 Charleroi Univ. Hospital	19	100%	100%	95%	79%
BE04 CHU Tivoli Hospital	19	100%	100%	100%	72%
BE06 Liege Rocourt Hospital	24	100%	100%	100%	100%
CH01 University Hospital Zürich	37	100%	100%	100%	100%
CH03 University Hospital Lucern	44	100%	100%	100%	100%
CH04 University Hospital Geneva	11	100%	100%	100%	91%
CH05 Lausanne University Hospital	23	100%	100%	100%	57%
CN01 Children's Hospital, Zheijang Univ.	6	100%	100%	100%	100%
CN02 Children's Hospital, Fudan	35	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CN03 Hainan Women and Children's Medical Center	5	100%	100%	100%	100%
CN04 Guangzhou Women and Children's Hospital	2	0%	0%	0%	0%
CN05 Longgang Distr. Centr. Hosp. Shenzen	10	100%	100%	100%	100%
CN06 Xiamen Children's Hospital	4	100%	100%	100%	100%
CN07 The People's Hospital of Dehong	3	100%	100%	100%	100%
CN08 Maternal and Child Health Hosp. Quangxi	7	100%	100%	100%	100%
CZ01 The Institute for the Care of Mother and Child	66	100%	100%	100%	97%
CZ02 Motol Univ. Hospital	10	100%	100%	100%	100%
DE01 University Hospital Freiburg	16	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
DK01 Rigshospitalet	106	100%	100%	100%	100%
DK04 Aalborg University Hospital	21	100%	100%	100%	100%
DK18 Aarhus University Hospital	22	100%	100%	100%	100%
DK30 Odense University Hospital	12	100%	100%	92%	100%
ES01 La Paz University Hospital	78	100%	100%	100%	99%
ES02 Hospital Clinic de Barcelona (Maternitat)	59	100%	100%	100%	100%
ES03 University Hospital 12 de Octubre	73	100%	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	32	100%	100%	100%	100%
ES06 H. U. Puerta del Mar	22	100%	100%	100%	100%
ES08 Hospital Clinico San Carlos	36	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES09 H. U. Marques de Valdecilla	23	100%	100%	100%	100%
ES10 Virgen de las Nieves	14	100%	100%	100%	100%
ES11 H. Univ. Juan XXIII Tarragona	18	61%	80%	61%	61%
ES12 Hospital Miguel Servet	1	100%	n/a	100%	100%
ES13 Hospital de Cruces	4	100%	100%	100%	100%
GR01 Alexandra Hospital, Athens	16	100%	100%	100%	100%
GR02 Ippokrateion Hospital of Thessalonikki	40	100%	100%	100%	100%
GR03 Univ of Patras, General Hospital	13	100%	100%	100%	100%
GR04 Univ Hospital of Heraklion	10	100%	100%	100%	100%
IE01 Univ. College Cork	22	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
IE02 Rotunda Hospital Dublin	19	100%	100%	100%	100%
IE03 Coombe Univ. Hospital	18	89%	100%	100%	94%
IE04 NMH Holles St	19	100%	100%	94%	100%
IN01 St Johns Medical College Hospital, Bangalore	5	100%	100%	100%	100%
IT01 Presidio Ospedale Sant'Anna, Turin	11	100%	100%	100%	100%
IT07 Fondazione IRCCS Milano	45	100%	100%	100%	100%
IT08 Ospedale del Ponte, Varese	12	100%	100%	100%	100%
IT09 Fondaz. Policlinico Univ. A Gemelli	15	100%	100%	100%	100%
NY10 Oslo University Hospital	36	100%	100%	91%	91%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
PL01 Medical Center UJASTEK Krakow	37	100%	100%	100%	100%
PL02 Wroclaw Medical University	1	100%	n/a	100%	100%
PL03 Specialist Hospital No. 2 Bytow	8	100%	100%	100%	100%
PL04 Poznan Univ. of Medical Sciences	34	100%	100%	100%	100%
PL06 Collegium Medicum in Bydgoszcz	3	100%	100%	67%	67%
PL07 Warsaw Univ. Medical Sciences	9	100%	100%	100%	100%
PL08 Szpital Uniwersytecki, Krakow	20	100%	100%	100%	95%
PL12 Centre of Medical Postgraduate Education, Warsaw	4	100%	100%	100%	100%
TR01 Gazi University Hospital	17	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR02 Marmara University Hospital	33	100%	100%	100%	100%
TR03 Uludag University Hospital	44	100%	100%	100%	100%
TR04 Kanuni Sultan Hospital	11	100%	100%	100%	100%
TR05 Bilkent, Ankara City Hospital	37	100%	100%	100%	100%
TR06 Basaksehir City Hospital	13	100%	100%	100%	100%
UK08 Royal Hospital for Children, Glasgow	21	100%	100%	100%	100%
UK09 NHS Lanarkshire Hospital	11	100%	100%	100%	100%
US02 Loma Linda Univresity Hospital	38	100%	100%	100%	97%
US03 University of Utah, Div. Neonatology	28	100%	100%	100%	100%
US04 UT Southwestern Medical Center	6	100%	100%	100%	100%
Total	1601	99%	99%	99%	98%

Site	Randomisations up until 16th of Dec 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
US05 Washington Univ. Hospital	**16**	**100%**	**100%**	**100%**	**100%**
Total	**1601**	**99%**	**99%**	**99%**	**98%**

Note that completion calculations are based on babies that have reached 3 days of life for end-of-monitoring completion and serious adverse reactions completion, and 36 weeks of postmenstrual age (PMA) for Follow-up and Blinded follow-up completion. The completion calculations are also based on babies eligible for data entry meaning that babies were consent has been declined/withdrawn are not included.

Investigators who do not have 100% completion of data entries across all three modules will be contacted by e-mail and asked to enter the missing data into OpenClinica.

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