SafeBoosC III Data completion report

18-July 2021

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 18th of July 2021. 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 data entries across all centres.

Note that completion calculations are based on babies that have reached at least 10 days of life for end-of-monitoring completion, and 40 weeks of postmenstrual age (PMA) for Follow-up and Blinded follow-up completion. n/a = not applicable, meaning that no babies at the specific site has reached 10 days of life or 40 weeks of PMA when applicable.

Site	Randomisations up until 18-July 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	14	100%	100%	100%	100%
BE01 Univ. Hospital Leuven	26	96%	91%	100%	96%
BE02 AZ St. Jain Univ. Hosp. Bruges	10	100%	100%	88%	88%

Site	Randomisations up until 18-July 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
BE03 Charleroi Univ. Hospital	7	100%	100%	100%	100%
BE04 CHU Tivoli Hospital	13	100%	83%	100%	90%
BE06 Liege Rocourt Hospital	19	95%	100%	85%	15%
CH01 University Hospital Zürich	37	100%	100%	100%	73%
CH03 University Hospital Lucern	34	97%	88%	100%	100%
CH04 University Hospital Geneva	9	89%	50%	100%	0%
CH05 Lausanne University Hospital	16	100%	100%	100%	0%
CN01 Children's Hospital, Zheijang Univ.	4	100%	100%	100%	0%
CN02 Children's Hospital, Fudan	35	100%	100%	100%	100%
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 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	2	100%	n/a	n/a	n/a
CN04 Guangzhou Women and Children's Hospital	2	0%	0%	n/a	n/a
CN05 Longgang Distr. Centr. Hosp. Shenzen	10	90%	80%	100%	100%
CN06 Xiamen Children's Hospital	4	100%	100%	100%	100%
CN07 The People's Hospital of Dehong	3	100%	100%	100%	33%
CN08 Maternal and Child Health Hosp. Quangxi	7	100%	100%	57%	57%
CZ01 The Institute for the Care of Mother and Child	54	100%	96%	100%	83%
CZ02 Motol Univ. Hospital	4	100%	n/a	100%	100%
DE01 University Hospital Freiburg	10	100%	100%	100%	100%
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 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	85	100%	98%	100%	100%
DK04 Aalborg University Hospital	14	100%	100%	100%	100%
DK18 Aarhus University Hospital	16	88%	100%	100%	90%
DK30 Odense University Hospital	9	89%	0%	89%	0%
ES01 La Paz University Hospital	68	100%	100%	100%	100%
ES02 Hospital Clinic de Barcelona (Maternitat)	47	100%	100%	100%	100%
ES03 University Hospital 12 de Octubre	57	100%	100%	95%	98%
ES05 Hospital de Sant Joan de Deu	26	96%	100%	100%	100%
ES06 H. U. Puerta del Mar	18	100%	100%	100%	100%
ES08 Hospital Clinico San Carlos	29	100%	93%	100%	100%
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 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	17	100%	100%	100%	79%
ES10 Virgen de las Nieves	11	100%	67%	100%	100%
ES11 H. Univ. Juan XXIII Tarragona	15	79%	100%	100%	100%
ES13 Hospital de Cruces	2	100%	100%	50%	100%
GR01 Alexandra Hospital, Athens	13	100%	100%	100%	100%
GR02 Ippokrateion Hospital of Thessalonikki	31	100%	100%	100%	100%
GR03 Univ of Patras, General Hospital	10	100%	100%	100%	100%
GR04 Univ Hospital of Heraklion	8	100%	100%	100%	100%
IE01 Univ. College Cork	16	93%	57%	86%	86%
IE02 Rotunda Hospital Dublin	3	100%	50%	n/a	n/a
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
IE03 Coombe Univ. Hospital	4	100%	0%	n/a	n/a
IE04 NMH Holles St	4	100%	0%	n/a	n/a
IN01 St Johns Medical College Hospital, Bangalore	4	100%	100%	100%	100%
IT01 Presidio Ospedale Sant'Anna, Turin	5	100%	100%	100%	100%
IT07 Fondazione IRCCS Milano	38	100%	94%	100%	100%
IT08 Ospedale del Ponte, Varese	4	100%	100%	100%	100%
IT09 Fondaz. Policlinico Univ. A Gemelli	8	100%	67%	100%	100%
NY10 Oslo University Hospital	16	69%	20%	100%	100%
PL01 Medical Center UJASTEK Krakow	32	100%	100%	100%	88%
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
PL03 Specialist Hospital No. 2 Bytow	6	100%	100%	100%	75%
PL04 Poznan Univ. of Medical Sciences	28	100%	93%	100%	100%
PL07 Warsaw Univ. Medical Sciences	9	100%	100%	100%	50%
PL08 Szpital Uniwersytecki, Krakow	14	100%	71%	100%	100%
PL12 Centre of Medical Postgraduate Education, Warsaw	4	33%	100%	n/a	n/a
TR01 Gazi University Hospital	13	100%	83%	100%	100%
TR02 Marmara University Hospital	29	100%	100%	100%	100%
TR03 Uludag University Hospital	31	93%	100%	100%	100%
TR04 Kanuni Sultan Hospital	11	100%	100%	100%	100%
Total	1185	97%	91%	99%	90%

Site	Randomisations up until 18-July 2021	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR05 Bilkent, Ankara City Hospital	36	82%	80%	100%	64%
TR06 Basaksehir City Hospital	8	100%	100%	100%	100%
UK08 Royal Hospital for Children, Glasgow	10	89%	75%	75%	100%
UK09 NHS Lanarkshire Hospital	4	100%	100%	100%	n/a
US02 Loma Linda Univresity Hospital	26	100%	100%	100%	82%
US03 University of Utah, Div. Neonatology	17	94%	100%	100%	100%
US04 UT Southwestern Medical Center	6	83%	100%	67%	67%
US05 Washington Univ. Hospital	3	100%	100%	n/a	n/a
Total	1185	97%	91%	99%	90%

Note that completion calculations are based on babies that have reached at least 10 days of life for end-of-monitoring completion, and 40 weeks of postmenstrual age (PMA) for Follow-up and Blinded follow-up completion. n/a = not applicable, meaning that no babies at the specific site has reached 10 days of life or 40 weeks of PMA when applicable.

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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