SafeBoosC III Data completion report

19-October 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 19th of October 2020. 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 19-October	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	**2**	**100%**	**100%**	**n/a**	**n/a**
BE01 Univ. Hospital Leuven	**10**	**100%**	**100%**	**100%**	**0%**
BE03 Charleroi Univ. Hospital	**4**	**100%**	**100%**	**n/a**	**n/a**

Site	Randomisations up until 19-October	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
BE04 CHU Tivoli Hospital	3	67%	0%	n/a	n/a
BE06 Liege Rocourt Hospital	1	0%	0%	n/a	n/a
CH01 University Hospital Zürich	19	100%	100%	100%	75%
CH03 University Hospital Lucern	17	75%	50%	89%	0%
CH04 University Hospital Geneva	5	100%	100%	100%	0%
CN02 Children's Hospital, Fudan	22	100%	88%	100%	100%
CN04 Guangzhou Women and Children's Hospital	1	0%	0%	n/a	n/a
CN05 Longgang Distr. Centr. Hosp. Shenzen	3	100%	100%	n/a	n/a
CN06 Xiamen Children's Hospital	1	n/a	n/a	n/a	n/a
CN07 The People's Hospital of Dehong	1	0%	n/a	n/a	n/a
Total	532	95%	89%	99%	87%

Site	Randomisations up until 19-October	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CN08 Maternal and Child Health Hosp. Quangxi	1	100%	n/a	n/a	n/a
CZ01 The Institute for the Care of Mother and Child	34	100%	100%	100%	81%
DE01 University Hospital Freiburg	3	100%	n/a	n/a	n/a
DK01 Rigshospitalet	63	97%	97%	100%	100%
DK04 Aalborg University Hospital	3	100%	100%	n/a	n/a
DK18 Aarhus University Hospital	4	100%	100%	50%	n/a
DK30 Odense University Hospital	3	33%	n/a	0%	0%
ES01 La Paz University Hospital	41	100%	100%	100%	100%
ES02 Hospital Clinic de Barcelona (Maternitat)	31	100%	100%	100%	100%
Total	532	95%	89%	99%	87%

Site	Randomisations up until 19-October	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES03 University Hospital 12 de Octubre	32	97%	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	19	100%	100%	100%	93%
ES06 H. U. Puerta del Mar	12	100%	100%	100%	90%
ES08 Hospital Clinico San Carlos	15	100%	88%	100%	100%
ES09 H. U. Marques de Valdecilla	10	20%	0%	100%	100%
ES10 Virgen de las Nieves	5	100%	100%	100%	100%
ES11 H. Univ. Juan XXIII Tarragona	9	100%	100%	100%	50%
GR01 Alexandra Hospital, Athens	9	100%	100%	100%	83%
GR02 Ippokrateion Hospital of Thessalonikki	18	100%	100%	100%	100%
GR03 Univ of Patras, General Hospital	7	100%	100%	100%	100%
Total	532	95%	89%	99%	87%

Site	Randomisations up until 19-October	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
GR04 Univ Hospital of Heraklion	4	100%	100%	100%	33%
IN01 St Johns Medical College Hospital, Bangalore	1	100%	n/a	n/a	n/a
IT01 Presidio Ospedale Sant'Anna, Turin	1	n/a	n/a	n/a	n/a
IT07 Fondazione IRCCS Milano	16	100%	71%	100%	100%
PL01 Medical Center UJASTEK Krakow	13	100%	100%	100%	100%
PL03 Specialist Hospital No. 2 Bytow	3	100%	n/a	100%	100%
PL04 Poznan Univ. of Medical Sciences	14	86%	43%	100%	100%
TR01 Gazi University Hospital	5	100%	100%	100%	80%
TR02 Marmara University Hospital	13	100%	100%	100%	100%
Total	532	95%	89%	99%	87%

Site	Randomisations up until 19-October	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR03 Uludag University Hospital	**13**	**100%**	**86%**	**100%**	**100%**
TR04 Kanuni Sultan Hospital	**11**	**100%**	**100%**	**100%**	**100%**
TR05 Bilkent, Ankara City Hospital	**24**	**100%**	**90%**	**100%**	**71%**
US02 Loma Linda Univresity Hospital	**4**	**100%**	**100%**	**n/a**	**n/a**
US03 University of Utah, Div. Neonatology	**2**	**100%**	**0%**	**n/a**	**n/a**
Total	**532**	**95%**	**89%**	**99%**	**87%**

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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