SafeBoosC III Data completion report

18-December 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 18th of December 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 18-December	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	**7**	**100%**	**100%**	**100%**	**100%**
BE01 Univ. Hospital Leuven	**13**	**100%**	**100%**	**67%**	**0%**
BE02 AZ St. Jain Univ. Hosp. Bruges	**3**	**100%**	**0%**	**n/a**	**n/a**

Site	Randomisations up until 18-December	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	5	100%	100%	100%	33%
BE04 CHU Tivoli Hospital	4	100%	100%	100%	0%
BE06 Liege Rocourt Hospital	2	100%	100%	n/a	n/a
CH01 University Hospital Zürich	26	100%	100%	100%	100%
CH03 University Hospital Lucern	21	100%	100%	100%	0%
CH04 University Hospital Geneva	7	100%	100%	100%	0%
CH05 Lausanne University Hospital	6	100%	0%	n/a	n/a
CN02 Children's Hospital, Fudan	28	100%	91%	82%	100%
CN04 Guangzhou Women and Children's Hospital	2	0%	0%	n/a	n/a
CN05 Longgang Distr. Centr. Hosp. Shenzen	5	100%	100%	100%	100%
Total	684	97%	92%	98%	89%

Site	Randomisations up until 18-December	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CN06 Xiamen Children's Hospital	2	100%	100%	n/a	n/a
CN07 The People's Hospital of Dehong	1	100%	n/a	n/a	n/a
CN08 Maternal and Child Health Hosp. Quangxi	3	100%	0%	100%	100%
CZ01 The Institute for the Care of Mother and Child	36	100%	100%	100%	71%
DE01 University Hospital Freiburg	6	100%	100%	100%	100%
DK01 Rigshospitalet	67	100%	100%	100%	100%
DK04 Aalborg University Hospital	5	100%	100%	100%	100%
DK18 Aarhus University Hospital	8	86%	75%	50%	100%
DK30 Odense University Hospital	6	25%	0%	0%	0%
Total	684	97%	92%	98%	89%

Site	Randomisations up until 18-December	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES01 La Paz University Hospital	53	100%	100%	100%	100%
ES02 Hospital Clinic de Barcelona (Maternitat)	37	100%	100%	100%	100%
ES03 University Hospital 12 de Octubre	35	100%	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	21	100%	100%	100%	100%
ES06 H. U. Puerta del Mar	15	100%	67%	100%	90%
ES08 Hospital Clinico San Carlos	21	100%	100%	100%	100%
ES09 H. U. Marques de Valdecilla	11	20%	0%	100%	100%
ES10 Virgen de las Nieves	6	100%	75%	100%	100%
ES11 H. Univ. Juan XXIII Tarragona	11	100%	100%	100%	100%
GR01 Alexandra Hospital, Athens	11	82%	100%	100%	100%
Total	684	97%	92%	98%	89%

Site	Randomisations up until 18-December	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
GR02 Ippokrateion Hospital of Thessalonikki	21	100%	100%	100%	100%
GR03 Univ of Patras, General Hospital	8	100%	100%	100%	100%
GR04 Univ Hospital of Heraklion	6	100%	67%	100%	100%
IN01 St Johns Medical College Hospital, Bangalore	3	100%	0%	100%	100%
IT01 Presidio Ospedale Sant'Anna, Turin	1	100%	100%	n/a	n/a
IT07 Fondazione IRCCS Milano	23	100%	100%	100%	100%
PL01 Medical Center UJASTEK Krakow	20	100%	100%	100%	100%
PL03 Specialist Hospital No. 2 Bytow	3	100%	n/a	100%	100%
PL04 Poznan Univ. of Medical Sciences	19	100%	100%	100%	50%
Total	684	97%	92%	98%	89%

Site	Randomisations up until 18-December	End-of-monitoring (72 hrs) % completed	Serious adverse reactions (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
PL07 Warsaw Univ. Medical Sciences	3	100%	0%	n/a	n/a
PL08 Szpital Uniwersytecki, Krakow	3	n/a	n/a	n/a	n/a
TR01 Gazi University Hospital	6	100%	100%	100%	100%
TR02 Marmara University Hospital	14	100%	100%	100%	100%
TR03 Uludag University Hospital	15	100%	100%	100%	100%
TR04 Kanuni Sultan Hospital	11	100%	100%	100%	100%
TR05 Bilkent, Ankara City Hospital	28	93%	83%	100%	85%
US02 Loma Linda Univresity Hospital	9	100%	100%	100%	100%
US03 University of Utah, Div. Neonatology	7	100%	100%	n/a	n/a
Total	684	97%	92%	98%	89%

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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