SafeBoosC III Data completion report

19-May 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 19th of May 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.

Site	Randomisations up until 19-May	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CH01 University Hospital Zürich	7	100%	100%	100%
CH 03 Univ. Hospital Lucern	8	80%	n/a	n/a
CN02 Children's Hospital, Fudan	4	100%	n/a	n/a
CZ01 The Institute for the Care of Mother and Child	15	100%	100%	92%
DK01 Rigshospitalet	44	100%	100%	100%
DK30 Odense Univ. Hosp.	1	0%	n/a	n/a
Total	247	97%	98%	93%

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-May	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES01 La Paz University Hospital	23	100%	100%	100%
ES02 Hospital Clinic de Barcelona (Maternitat)	19	100%	100%	100%
ES03 University Hospital 12 de Octubre	25	100%	95%	100%
ES05 Hospital de Sant Joan de Deu	11	91%	100%	100%
ES06 H. U. Puerta del Mar	9	100%	100%	0%
ES08 C. H. Universitario de Santiago	10	100%	100%	100%
ES09 H. U. Marques de Valdecilla	2	100%	0%	100%
ES10 Virgen de las Nieves	3	100%	n/a	n/a
ES11 H. Univ. Juan XXIII Tarragona	5	100%	n/a	n/a
Total	247	97%	98%	93%

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-May	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
GR01 Alexandra Hospital, Athens	3	0%	n/a	n/a
GR02 Ippokrateion Hospital of Thessalonikki	9	100%	100%	80%
GR03 Univ of Patras, General Hospital	2	100%	n/a	n/a
IT07 Fondazione IRCCS Milano	12	100<5	100%	100%
PL01 Medical Center UJASTEK Krakow	6	100%	n/a	n/a
PL04 Poznan Univ. Medical Sciences	3	50%	n/a	n/a
TR01 Gazi Univ. Hospital	4	100%	100%	0%
TR02 Marmara Univ. Hospital	7	100%	100%	100%
TR03 Uludag Univ. Hospital	1	n/a	n/a	n/a
Total	247	97%	98%	93%

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-May	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
TR04 Kanuni Sultan Hospital	**7**	**100%**	**100%**	**0%**
TR05 Bilkent, Ankara City Hospital	**7**	**100%**	**100%**	**0%**
Total	**247**	**97%**	**98%**	**93%**

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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