

SafeBoosC III Data completion report

20-March 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 20th of March 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 20-March	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CH01 University Hospital Zürich	6	100%	n/a	n/a
CH 03 Univ. Hospital Lucern	3	0%	n/a	n/a
CZ01 The Institute for the Care of Mother and Child	13	100%	100%	100%
DK01 Rigshospitalet	37	100%	100%	100%
ES01 La Paz University Hospital	19	100%	100%	100%
Total	175	98%	100%	99%

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 20- March	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES02 Hospital Clinic de Barcelona (Maternitat)	14	100%	100%	100%
ES03 University Hospital 12 de Octubre	24	100%	100%	100%
ES05 Hospital de Sant Joan de Deu	8	100%	100%	100%
ES06 H. U. Puerta del Mar	4	100%	100%	0%
ES08 C. H. Universitario de Santiago	8	100%	100%	100%
ES09 H. U. Marques de Valdecilla	2	100%	n/a	n/a
ES10 Virgen de las Nieves	3	n/a	n/a	n/a
ES11 H. Univ. Juan XXIII Tarragona	1	100%	n/a	n/a
GR02 Ippokrateion Hospital of Thessalonikki	7	100%	100%	100%
Total	175	98%	100%	99%

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 20-ja	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
IT07 Fondazione IRCCS Milano	7	100%	n/a	n/a
PL01 Medical Center UJASTEK Krakow	2	100%	n/a	n/a
TR01 Gazi Univ. Hospital	3	100%	n/a	n/a
TR02 Marmara Univ. Hospital	4	100%	n/a	n/a
TR04 Kanuni Sultan Hospital	5	100%	n/a	n/a
TR05 Bilkent, Ankara City Hospital	5	75%	n/a	n/a
Total	175	98%	100%	99%

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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