

SafeBoosC III Data completion report

19-June 2020

The data shown below is based on all registered data entries in OpenClinica on SafeBoosC III trial participants, up until 19th of June 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-June	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
CH01 University Hospital Zürich	9	100%	100%	100%
CH 03 Univ. Hospital Lucern	9	89%	100%	0%
CH04 Univ. Hospital Geneva	3	n/a	n/a	n/a
CN02 Children’s Hospital, Fudan	7	86%	n/a	n/a
CN04 Guangzhou Women and Children’s Hospital	1	n/a	n/a	n/a
CZ01 The Institute for the Care of Mother and Child	20	100%	100%	92%
Total	302	91%	99%	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-June	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
DK01 Rigshospitalet	47	100%	100%	100%
DK30 Odense Univ. Hosp.	3	50%	n/a	n/a
ES01 La Paz University Hospital	26	100%	100%	100%
ES02 Hospital Clinic de Barcelona (Maternitat)	24	100%	100%	100%
ES03 University Hospital 12 de Octubre	27	96%	96%	96%
ES05 Hospital de Sant Joan de Deu	11	100%	100%	88%
ES06 H. U. Puerta del Mar	11	100%	100%	100%
ES08 C. H. Universitario de Santiago	11	100%	100%	100%
Total	302	91%	99%	93%

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Site	Randomisations up until 19-June	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
ES09 H. U. Marques de Valdecilla	2	100%	100%	100%
ES10 Virgen de las Nieves	3	100%	n/a	n/a
ES11 H. Univ. Juan XXIII Tarragona	6	100%	n/a	n/a
GR01 Alexandra Hospital, Athens	4	0%	n/a	n/a
GR02 Ippokrateion Hospital of Thessalonikki	11	100%	100%	71%
GR03 Univ of Patras, General Hospital	4	100%	n/a	n/a
GR04 Univ Hospital of Heraklion	2	100%	n/a	n/a
IT07 Fondazione IRCCS Milano	14	86%	100%	100%
PL01 Medical Center UJASTEK Krakow	7	100%	100%	75%
Total	302	91%	99%	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-June	End-of-monitoring (72 hrs) % completed	Follow-up (36 weeks) % completed	Blinded follow-up (brain ultrasound) % completed
PL03 Specialist Hospital No. 2 Bytow	2	100%	n/a	n/a
PL04 Poznan Univ. Medical Sciences	4	50%	n/a	n/a
TR01 Gazi Univ. Hospital	4	100%	100%	100%
TR02 Marmara Univ. Hospital	8	100%	100%	100%
TR03 Uludag Univ. Hospital	2	0%	n/a	n/a
TR04 Kanuni Sultan Hospital	9	100%	100%	100%
TR05 Bilkent, Ankara City Hospital	10	90%	100%	60%
Total	302	91%	99%	93%

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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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