

Modification of the definition of bronchopulmonary dysplasia

The first participant in the SafeBoosC-III trial was randomised on the 27th of June 2019 in Copenhagen University Hospital. At that time point, the definition of bronchopulmonary dysplasia (BPD) was:

“oxygen or ventilator/continued positive airway pressure (CPAP) requirement at the time of assessment”

On the 6th of September 2019, the principal investigator from Copenhagen University Hospital raised a concern that the present definition of BPD was unclear, since it did not include nasal high flow therapy. The coordinating investigator stated that nasal high flow therapy was intended to be included in the BPD. Therefore, to make this clearer, the wording/definition of BPD was changed to

“any respiratory support and/or supplemental oxygen requirement at the time of assessment”

This was registered as an amendment in the pending protocol version 1.2.3 (amendments are not submitted to local IRB/REBs yet) and changed accordingly in the electronic case report form (6th of September 2019).

At that time point, 17 babies had been randomised and for two of them, data on BPD had been entered. The assessment of BPD for both babies was based on the modified definition.

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