GCP ENHEDEN
AALBORG OG AARHUS UNIVERSITETSHOSPITALER

Data Verification Plan
HOT-ICU
"Handling Oxygenation Targets in the Intensive Care Unit"
EudraCT-no. 2017-00632-34

Level I: Systematic data verification of all data collected. Applies to the first 3 trial participants and hereafter on every 10th randomly chosen trial participant.
Level II: All trial participants.

Data	eCRF Code/page	I	II	Comments
Informed consent		x	x	
Consent stated in medical record		x	x	
Inclusion criteria	S1-S7	x	x	
Exclusion criteria	S8-S19	x		
Randomisation	S20-S25	x	x	
Baseline				
General Patient Information	B1-B6	x		B4: Check only for presence of data.
Respiratory support	B7-B7d	x		Appears in the eCRF if S4 = "Yes".
Arterial Blood Gas	B8-B11	x		Last value before randomisation.
Acute Illness	B12-B18	x		B18: Check only for presence of data.
Sofa score	B19-B26	x		B19, B20 and B25: Check only for presence of data.
Chronic co-morbidities	B27-B30a	x		B28 and B30a: Check only for presence of data.

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Data	eCRF Code/page	I	II	Comments
Daily registration				
Respiratory support	D1	x[1]	x[1]	D1: Invasive mechanical ventilation, NIV or CPAP (intermittent CPAP = less than one hour is not regarded as respiratory support).
Use of prone position, inhaled vasodilators or ECMO	D1a-D1c	x[1]		
06.00h – 05.59h	D2-D5b	x[1]		
Respiratory status 08:00	D6-D7a4	x[1]		
Remaining organ systems	D8	x[1]		
Remaining organ systems	D9, D10 and D14	x[1]		
SAE/secondary outcome (Defined as acute myocardial ischaemia, ischemic stroke, intestinal ischaemia or a new incidence of shock)	D11-D13	x[1]	x[1]	Hospital records are reviewed for the first 7 days of admission. In case of an SAE, check eCRF for correct registration.
x[1]: Check the first 7 daily forms and hereafter every 5th daily form				
Discharge from ICU	DR1-DR3	x		
Readmission	DR4-DR5	x		Within 90 days from randomisation
Withdrawal	W1-W3b	x		NOTE! It should be stated in the patient's medical record whether consent is given to keep up data registration when written consent for trial participation is retracted or not given
Follow up/primary outcome after 90 days		x	x	

APPROVED
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