GCP ENHEDEN
AALBORG OG AARHUS UNIVERSITETSHOSPITALER

Data Verification Plan
HOT-COVID
"Handling Oxygenation Targets in COVID-19"
EudraCT-no. 2017-00632-34

Level I: Systematic data verification of all data collected. Applies to 5% of trial participants.
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	S2-S7	x	x	
Exclusion criteria	S8-S19	x		
Randomisation	S20-S1	x	x	
Baseline				
General Patient Information	B1-B6	x		B4: Check only for presence of data.
Oxygen supplementation	B7	x		
Respiratory support	B7a1-B7ac	x		Appears in the eCRF if B7a = "Invasive MV".
Respiratory support	B7a4	X		Appears in the eCRF if B7a = "NIV or CPAP".
Arterial Blood Gas	B8-B11	x		Last value before randomisation.
Acute Illness	B12-B18 EX1	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-B32	x		B28 and B30a: Check only for presence of data.

GCP ENHEDEN
AALBORG OG AARHUS UNIVERSITETSHOSPITALER

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	x	Hospital records are reviewed for the first 4 days of admission. In case of an SAE, check eCRF for correct registration.
x[1]: Check the first 4 daily forms and hereafter every 10th 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
90 days follow-up				
Status at 90 days follow-up	F1-F2	x		
Follow up/primary outcome after 90 days	F3-F7a1	x		

FEBRUARY,
AALBORG 1ST 2021

Professor, overlæge, ph.d.
Bodil Steen Rasmussen
Anæstesi og Intensiv Afdeling