



Place in Site Master File #9a

Instruction for the HOT-ICU trial - eligibility

Inclusion criteria

- ✓ **Acute admission to the ICU, and**
 - ✓ **Aged 18 years or above, and**
 - ✓ **One of the following:**
 - **Respiratory support in a closed system with an $FiO_2 \geq 0.50$**
(Closed systems: invasive mechanical ventilation, non-invasive ventilation or CPAP)
 - **Oxygen supplementation in an open system with an oxygen flow ≥ 10 litres per minute**
(Open System: Any oxygen supplementation which is not defined as a closed system in the above. Includes high-flow systems)
- and**
- ✓ **Oxygen supplementation in the ICU expected to last ≥ 24 hours. When in doubt of this forecast the patient should be enrolled**
 - ✓ **Intra-arterial catheter in place**

Exclusion criteria

× > 12 hours since ICU admission

(If the patient was transferred directly from another ICU the 12 hour period start at the time of admission to the first ICU)

× Chronic mechanical ventilation

(Invasive mechanical ventilation, continuous non-invasive ventilation or continuous mask-CPAP. Nocturnal CPAP or non-invasive ventilation due to sleep apnea and/or obesity hypoventilation syndrome is not regarded as chronic mechanical ventilation)

× Use of home oxygen

(Any daily prescribed supplementary oxygen inhalation given continuously, in daytime or nocturnally)

× Previous treatment with bleomycin

(Any history of bleomycin treatment documented in the patient charts)

× Organ transplant during current hospital admission

(Any kind of solid organ transplant is planned or has been conducted)

× Withdrawal from active therapy or brain death deemed imminent

× Fertile woman with positive urine or plasma hCG

(In all fertile woman < 50 years of age, a negative hCG-test must be present before screening)

× Carbon monoxide poisoning

(Confirmed by an arterial or venous blood carboxyhaemoglobin > 3% for non-smokers and > 10% for active smokers during current hospitalisation)

× Cyanide poisoning

(If suspected by the clinicians during current hospitalisation and documented in the patient charts)

× **Paraquat poisoning**

(If suspected by the clinicians during current hospitalisation and documented in the patient charts)

× **Methaemoglobinaemia**

(A confirmed arterial or venous blood methaemoglobin > 8% during current hospitalisation)

× **Sickle cell disease**

(Any history of sickle cell disorder documented in patient charts or the presence of haemoglobin S (HbS) in an arterial or a venous blood sample)

× **Expected use of hyperbaric oxygen treatment**

(Confirmed by an arterial or venous blood carboxyhaemoglobin > 3% for non-smokers and > 10% for active smokers during current hospitalisation)

× **Consent according to national regulations not obtainable**

× **Previously randomised into the HOT-ICU trial**

(Previously screened patients are eligible if they were never randomised)