**Primary data source**

**Protocol:** Handling Oxygenation Targets in the Intensive Care Unit (HOT-ICU)

**Department:**

**Hospital:**

**Investigator:**

|  |  |
| --- | --- |
| **Data** | **Primary data source** |
| Concent |  |
| **SCREENING FORM** |  |
| Participant ID |  |
| **INCLUSION CRITERIA** |  |
| Akute Admission |  |
| Age |  |
| Oxygen supplementation, closed/open system |  |
| Expected duration | Clinical judgement |
| Arterial line |  |
| **EXCLUSION CRITERIA** |  |
| Time since ICU-admission |  |
| Chronic mechanical ventilation |  |
| Home oxygen use |  |
| Previous bleomycin treatment |  |
| Organ transplant |  |
| Withdrawn therapy/imminently brain dead |  |
| hCG test |  |
| Carbon monoxide poisoning |  |
| Cyanide poisoning |  |

|  |  |
| --- | --- |
| **Data** | **Primary data source** |
| Paraquat poisoning |  |
| Methaemoglobinaemia |  |
| Sicle cell disease |  |
| Expected use of hyperbaric oxygen |  |
| Lack of consent |  |
| Previously enrolled in the HOT-ICU trial |  |
| **STRATIFICATION VARIABLES** |  |
| Chronic Obstructive Pulmonary Disease |  |
| Active haematological malignancy |  |
| Randomisation | eCRF |
| Time of randomisation | eCRF |
| **BASELINE FORM** |  |
| **GENERAL PATIENT INFORMATION** |  |
| Date and time of admission |  |
| Admission directly from the operating or recovery room after surgery |  |
| Patient height |  |
| **RESPIRATORY SUPPORT** |  |
| Type of closed system (Invasive MV, NIV or CPAP) |  |
| TVinsp, PEEP, Ppeak, EPAP or CPAP |  |
| **ARTERIAL BLOOD GAS BEFORE RANDOMISATION** |  |
| PaO2, SaO2,FiO2 |  |
| P(ab) Lactate |  |
|  |  |
| **ACUTE ILLNESS** |  |
| Pneumonia, multi trauma, stroke, traumatic brain injury, myocardial infarction, intestinal ischaemia, ARDS (Acute Respiratory Distress Syndrome) at randomisation |  |
| **SOFA SCORE** |  |
| Glascow Coma Scale |  |
| Mean arterial blood pressure (MAP) |  |
| Dobutamine, milrinone and/or levosimendan within 24 hours before randomisation |  |
| Contnously infused vasopressor within 24 hours before randomisation |  |
| Highest dose of dopamine/norepinephrine/epinephrine within 24 hours before randomisation |  |
| Highest bilirubin within 24 hours before randomisation |  |
| Lowest platelets within 24 hours before randomisation |  |
| Urinary output |  |
| Højeste creatinine within 24 hours before randomisation |  |
| **CHRONIC CO-MORBIDITIES** |  |
| History of ischaemic heart disease |  |
| Chronic heart failure |  |
| Metastatic cancer |  |
| Chronic dialysis   * Habitual creatinine level > 110 µmol/L |  |
|  |  |
|  |  |
|  |  |
| **DAILY FORM** |  |
| **TIME SPAN** |  |
| Date/time | eCRF |
| **RESPIRATION** |  |
| Respiratory support. If yes   * Mechanical ventilation in prone position * inhaled vasodilators (Prostacyclin/PGI2, Nitrogenoxid/NO) * ECMO |  |
| **06:00 – 18:00, 18:00-06:00** |  |
| Highest PaO2. If value registered   * Concomitant SaO2 og FiO2 * Lowest PaO2with concomitant SaO2 and FiO2 |  |
| **ABGs** |  |
| Totalt number of arterial blood gas samples on this day |  |
| **RESPIRATORY EVENTS 08:00** |  |
| Respiratory support at 08:00h on this day. If yes   * Invasive MV. If yes * TVinsp * PEEP * Ppeak * NIV or CPAP. If yes   + EPAP eller CPAP |  |
| **REMAINING ORGAN SYSTEMS** |  |
| Highest lactate (fra kl.06:00-06:00) |  |
| Circulatory support (vasopressor/inotropes) |  |
| Renal replacement therapy |  |
| Myocardial ischaemia |  |
| Ischaemic stroke |  |
|  |  |
| Intestinal ischaemia |  |
| Units of red blood cells transfused |  |
| **DISCHARGE AND READMISSION FORM** |  |
| Date/time | eCRF |
| Discharged to |  |
| Inclusion in other interventional trials |  |
| Date/time of possible readmission |  |
| **WITHDRAWAL FORM** |  |
| Date/time | eCRF |
| SUSAR |  |
| Consent not given/further data registration |  |
| **90 DAYS FOLLOW-UP** |  |
| Date | eCRF |
| Discharged from hospital within 90 days. If yes   * Date of discharge * Readmission to hospital within 90 days/cumulated number of days |  |
| Dead |  |

Investigator (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions**

The primary data source list is used by the Good clinical practice (GCP) monitors in order to check that entered data are correct. The primary data source refers to the source/place where the data first appears (original data capture). Data sources must be listed for all data in the eCRF in the primary data source list above, prior to inclusion of the first patient. Data may have more than one data source. In this case all sources should be listed. The superior sources should be listed first in case the data differs between sources.

The Primary Data Source List must be signed by the local investigator before initiating the trial and filed in “Site Master File”. If the list is updated during the trial, please remember to place the new list in the Site Master File.

**Examples of data**

Previous diseases, inclusion/exclusion criteria, randomisation number, date of visit, clinical examination, ECG, blood pressure, laboratory tests, drugs, side-effects, etc.

**Examples of sources from which data are captured - electronic or hard-copy documents**

Analysis print, ECG-print, electronic medical record, e-CRF, nurse notes, X-ray memorandum etc.

Describe the source as specific as possible.