**Kildedataliste**

**Protokoltitel: Low-dose hydrocortisone in patients with COVID-19 and severe hypoxia – the COVID STEROID Trial**

**Afdeling:**

**Hospital:**

**Investigator:**

|  |  |  |
| --- | --- | --- |
|  | **Data** | **Primary data source** |
|  | Consent |  |
|  | **SCREENING FORM** |  |
| S1 | National identification number |  |
|  | **Inclusion criteria** |  |
| S2 | Age |  |
| S3 | Does the patient have documented COVID-19 |  |
| S4 | Oxygen supplementation through an open system with an oxygen flow of at least 10 L/minORRespiratory support in a closed system |  |
|  | **Either of the following inclusion criteria must be fulfilled** |  |
| S5 | Respiratory support in a closed system |  |
| S5a | Invasive mechanical ventilation |  |
| S5b | Non-invasive ventilation |  |
| S5c | Continuous CPAP (NOT including intermittent CPAP) |  |
|  | **Exclusion criteria** |  |
| S6 | Has the patient received invasive mechanical ventilation for more than 48 hours at the time of screening? |  |
| S7 | Does the patient have an indication for use of systemic corticosteroids? |  |
| S8 | Does the patient have a documented invasive fungal infection? |  |
| S9 |  Is the patient pregnant? |  |
| S10 |  Known hypersensitivity to hydrocortisone? |  |
| S11 | Has the clinical team decided not to use invasive mechanical ventilation for this patient? |  |
| S12 | Consent unobtainable according to national regulations? |  |

|  |  |  |
| --- | --- | --- |
|  | **BASELINE FORM** |  |
|  | **GENERAL PATIENT INFORMATION** |  |
| BL1 | Sex |  |
| BL2 | Hospital admission date? |  |
| BL3 | Number of days with symptoms before hospital admission |  |
| BL4 | Department at which the participant was included |  |
|  | **Co-morbidities** |  |
| BL5 | History of ischemic heart disease or heart failure? |  |
| BL6 | History of chronic hypertension? |  |
| BL7 | Chronic pulmonary disease? |  |
| BL8 | Diabetes Mellitus? |  |
|  | **Blood values, interventions and vital parameters** |  |
| BL9 | Participant weight |  |
| BL10 | Use of any form of renal replacement therapy within the last 72 hours prior to randomisation: |  |
| BL11 | Infusion of vasopressor/inotropic agent to increase mean arterial blood pressure within the last 24 hours prior to randomisation |  |
| BL12 | Use of respiratory support on a closed system at randomization? |  |
| BL12a | If YES, what was the latest FiO2 prior to randomization? |  |
| BL12b | If YES, How many hours prior to randomization |  |
| BL12c | If NO, what was the maximum supplemental oxygen flow on an open system at randomisation (+/- 1 h) |  |
| BL13 | Most recent PaO2 prior to randomisation |  |
| BL14 | Most recent arterial O2 saturation prior to randomization? |  |
| BL15 | Highest plasma lactate value in the last 24 hours prior to randomisation: |  |
|  | **Co-interventions** |  |
| BL16 | Agents with potential anti-inflammatory action? |  |
| BL16a | If YES, then Corticosteroids? |  |
| BL16b | If YES, then Interleukin-6 inhibitor? |  |
| BL16c | If YES, then other? |  |
| BL17 | Use of any drug with potential antiviral activity in the 14 days prior to randomisation? |  |
| BL17a | If YES, then Remdesivir? |  |
| BL17b | If YES, then Hydroxychloroquin? |  |
| BL17c | If YES, then Lopinavir/ritonavir? |  |
| BL17d | If YES, then convalescence plasma? |  |
| BL17e | If YES, then other systemic antiviral drug? |  |
| BL18 | Use of any systemic anti-bacterial drugs in the 24 h prior to randomisaton? |  |
|  |  |  |
|  |  |  |
|  | **DAY FORM day 1-7** |  |
|  | **Time span** |  |
|  | Date/time |  |
|  | **Major protocol violations on this day** |  |
| D1 | Was the trail medication delivered to the patient on this day as per protocol? |  |
| D1a | If YES in D1, as continuous infusion or boli? |  |
| D1b | If NO in D1, did the patient receive any trial medication? |  |
| D1ba | If YES in D1b, what was the estimated cumulated dose of trial medication on this day? |  |
|  | **Reason(s) for violation of protocol on this day** |  |
| D1c | If NO in D1, due to error/lack of resources? |  |
| D1d | If NO in D1, due to patient withdrawal for the intervention? |  |
| D1e | If NO in D1, due to patient discharged to a COVID STEROID non-trial site? |  |
| D1f | If NO in D1, due to other |  |
| D2 | Treatment with open-label systemic corticoroids on this day? |  |
|  | **Co-interventions** |  |
| D3 | Did the patient receive invasive mechanical ventilation on this day? |  |
| D4 | Did the patient receive infusion of vasopressor or inotropes for at least one hour of this day? |  |
| D5 | Did the patient receive renal replacement therapy on this day? |   |
|  | **Serious Advers Events/Reactions** |  |
| SAR1 | Clinically important gastrointestinal bleeding on this day? |  |
| SAR2 | New onset septic shock on this day? |  |
| SAR3 | Invasive fungal infection on this day? |  |
| SAR4 | Anaphylactic reaction to IV hydrocortison? |  |

|  |  |  |
| --- | --- | --- |
|  | **DAY FORM day 8-14** |  |
|  | **Time span** |  |
|  | Date/time |  |
|  | **Major protocol violations on this day** |  |
| Dx1 | Treatment with open-label systemic corticosteroids on this day? |  |
|  | **Co-interventions** |  |
| Dx2 | Did the patient receive invasive mechanical ventilation on this day? |  |
| Dx3 | Did the patient receive infusion of vasopressors or inotropes for at least one hour on this day? |  |
| Dx4 | Did the patient receive invasive mechanical ventilation on this day? |   |
|  | **Serious Advers Events/Reactions** |  |
| SAR1 | Clinically important gastrointestinal bleeding on this day? |  |
| SAR2 | New onset septic shock on this day? |  |
| SAR3 | Invasive fungal infection on this day? |  |
| SAR4 | Anaphylactic reaction to IV hydrocortison? |  |

|  |  |  |
| --- | --- | --- |
|  | **DISCHARGE AND READMISSION FORM** |  |
| 1 | Date/time |  |
| 2 | Discharged to |  |
| 3 | Date/time of possible readmission |  |

|  |  |  |
| --- | --- | --- |
|  | **WITHDRAWAL FORM** |  |
|  | Date/time |  |
|  | Reason |  |
|  | Consent not given/further data registration |  |

|  |  |  |
| --- | --- | --- |
|  | **28 DAYS FOLLOW-UP** |  |
| FU1 | Date |  |
| FU2 | Did the patient die within 28 days of follow-up? |  |
| FU2a | Date of death? |  |
|  | **Duration of life-support to day 28** |  |
| FU3 | How many days from day 15 – 28 did the patient receive invasive mechanical ventilation? |  |
| FU4 | How many days from day 15 – 28 did the patient receive vasopressors or inotropes? |  |
| FU5 | How many days from day 15 – 28 did the patient receive renal replacement therapy? |  |
| FU6 | How many days from **randomisation** to day 28 did the patient receive ECMO therapy? |  |

|  |  |  |
| --- | --- | --- |
|  | **90 DAYS FOLLOW-UP** |  |
| FU1 | Date |  |
| FU2 | Did the patient die within 28 days of follow-up? |  |
| FU2a | Date of death? |  |
|  | **Length of hospital stay at day 90** |  |
| FU3 | Discharged alive from the hospital within 90 days |  |
| FU3a | Date of hospital discharge (index admission) |  |
|  | **Duration of life-support to day 90** |  |
| FU4 | How many days from day 29 – 90 did the patient receive invasive mechanical ventilation? |  |
| FU5 | How many days from day 29 – 90 did the patient receive vasopressors or inotropes? |  |
| FU6 | How many days from day 29 – 90 did the patient receive renal replacement therapy? |  |

|  |  |  |
| --- | --- | --- |
|  | **1-year FOLLOW-UP FORM** |  |
| FU1 | Date |  |
| FU2 | Was the patient dead on the date of follow-up? |  |
| FU2a | Date of death? |  |
|  | **Quality of life at 1-year post-randomisation** |  |
| FU3 | Lost to HRQoL follow-up? |  |
| FU3a | Date of EQ-5D-5L and EQ-VAS interviews |  |
| FU5-10 | EQ-5D-5L and EQ-VAS score |  |
| FU11 | HRQoL follow-up conducted by proxy? |  |