**Kildedataliste**

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

**Afdeling: 4131**

**Hospital: Rigshospitalet**

**Investigator: Marie Warrer Petersen**

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|  | **Data** | **Primary data source** |
|  | Consent | Samtykkeerklæring |
|  | **SCREENING FORM** |  |
| S1 | National identification number | SP-Header |
|  | **Inclusion criteria** |  |
| S2 | ≥18 years old | SP-Header |
| S3 | Documented COVID-19 | SP-Forside -> rapportindex -> diagnoser |
| S4 | Oxygen supplementation through an open system with an oxygen flow of at least 10 L/min | SP- Vurderingsskema -> resp |
|  | **Either of the following inclusion criteria must be fulfilled** |  |
| S5 | Respiratory support in a closed system | SP- Vurderingsskema -> resp |
| S5a | Invasive mechanical ventilation | SP- Vurderingsskema -> resp |
| S5b | Non-invasive ventilation | SP- Vurderingsskema -> resp |
| S5c | Continuous CPAP (NOT including intermittent CPAP) | SP- Vurderingsskema -> resp |
|  | **Exclusion criteria** |  |
| S6 | Has the patient received invasive mechanical ventilation for more than 48 hours at the time of screening? | SP- Vurderingsskema -> resp |
| S7 | Does the patient have an indication for use of systemic corticosteroids? | 1) SP-Resume -> MDA historik2) SP-Indlæggelses notat/resume |
| S8 |  Invasive fungal infection? | 1) SP-Resultater -> resultatgennemgang2) SP-Resultater -> mere -> parakliniske systemer -> mikrobiologi3) SP-forside -> rapportindeks -> Diagnoser |
| S9 |  Plasma hCG or urine-hCG (women <60 years) | SP-Notater (stud med. sikrer sig der er lavet urin stix og laver notat om svaret) |
| S10 |  Known hypersensitivity to hydrocortisone? | SP-Header: Cave |
| S11 |  Has the clinical team decided not to use invasive mechanical ventilation for this patient? | SP- Header: Beh. niveau |
| S12 |  Consent unobtainable according to national regulations? | SP-Notater |

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|  | **BASELINE FORM** |  |
|  | **GENERAL PATIENT INFORMATION** |  |
| BL1 | Sex | SP-Header |
| BL2 | Hospital admission date? | SP -> vis journal -> behandlingskontakter -> flueben i indlæggelser |
| BL3 | Number of days with symptoms before hospital admission | 1) SP – Resumé 2) SP- indlæggelsesnotat |
| BL4 | Department at which the participant was included | SP - forskningsnotat |
|  | **Co-morbidities prior to hospital admission** |  |
| BL5 | History of ischemic heart disease or heart failure? | 1) SP- Diagnoseliste2) SP – Resume / indlæggelsesnotat |
| BL6 | History of chronic hypertension? | 1) SP- Diagnoseliste2) SP – Resume / indlæggelsesnotat |
| BL7 | Chronic pulmonary disease? | 1) SP- Diagnoseliste2) SP – Resume / indlæggelsesnotat |
| BL8 | Diabetes Mellitus? | 1) SP- Diagnoseliste2) SP – Resume / indlæggelsesnotat |
|  | **Baseline data** |  |
| BL9 | Participant weight | 1) SP- forside -> søg (indtast ’vægt’ i øvre højre hjørne)2) estimer med klinisk blik eller via personalet |
| BL10 | Use of any form of renal replacement therapy within the last 72 hours prior to randomisation: | 1. SP-Vurderingsskema ’CRRT’
2. SP – Notater

3) SP – Resume – ’Dialyse og CRRT overblik’ |
| BL11 | Infusion of vasopressor/inotropic agent to increase mean arterial blood pressure within the last 24 hours prior to randomisation | SP-Resume -> MDA historik |
| BL12 | Use of respiratory support on a closed system at randomization? | SP- Vurderingsskema -> resp |
| BL12a | If YES, what was the latest FiO2 prior to randomization? | SP- Vurderingsskema -> resp |
| BL12b | If YES, How many hours prior to randomization | SP- Vurderingsskema -> resp |
| BL12c | If NO, what was the maximum supplemental oxygen flow on an open system at randomisation (+/- 1 h) | SP- Vurderingsskema -> resp |
| BL13 | Most recent PaO2 prior to randomisation | SP- resultater |
| BL14 | Most recent arterial O2 saturation prior to randomization? | 1) SP- resultater2) SP-vurderingsskema -> resp |
| BL15 | Highest plasma lactate value in the last 24 hours prior to randomisation: | SP- resultater -> søg ‘laktat’, men OBS der vil ofte være 2 eller 3 laktat variable derfor scroll op/ned |
|  | **Co-interventions** |  |
| BL16 | Agents with potential anti-inflammatory action during current hospital admission? | SP-Resume -> MDA historik |
| BL16a | If YES, then Corticosteroids? | SP-Resume -> MDA historik |
| BL16b | If YES, then Interleukin-6 inhibitor? | SP-Resume -> MDA historik |
| BL16c | If YES, then other? | SP-Resume -> MDA historik |
| BL17 | Use of any drug with potential antiviral activity during current hospital admission? | SP-Resume -> MDA historik |
| BL17a | If YES, then Remdesivir? | SP-Resume -> MDA historik |
| BL17b | If YES, then Hydroxychloroquin? | SP-Resume -> MDA historik |
| BL17c | If YES, then Lopinavir/ritonavir? | SP-Resume -> MDA historik |
| BL17d | If YES, then convalescence plasma? | 1) SP-Notater2) SP-Resume -> MDA historik |
| BL17e | If YES, then other systemic antiviral drug? | SP-Resume -> MDA historik |
| BL18 | Use of any systemic anti-bacterial drugs during current hospital admission? | SP-Resume -> MDA historik |
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|  | **TRIAL MEDICATION Days 1-8** |  |
|  | **Administered Trial Medication** |  |
| ATM1 | Did the patient receive trial medication on this day? (yes/no) | SP-Resume -> MDA-historikSP-Resume -> MDA-overblik |
| ATM1a | If YES in ATM1, how was the trial medication delivered on this day? (continuous infusion, bolus injections, both) | SP-Resume -> MDA-historikSP-Resume -> MDA-overblik |
| ATM1b | If YES in ATM1, did the patient receive at least 50% of the planned volume on this day? (yes/no) | 1. SP -> indgift/udskillelse
2. SP-Resume -> MDA-historik eller SP-Resume -> MDA-overblik og SP-Vurderingsskema
3. Visuel inspektion af forsøgsmedicin på patientens stue. Dokumenteres i medicinlog.
 |
|  | **Reason(s) for violation of protocol on this day** |  |
| ATM1c | If NO in ATM1 or ATM1b, by error/lack of resources? | 1) SP-Notater2) Spørg personalet  |
| ATM1d | If NO in ATM1 or ATM1b, due to other reasons? | 1) SP-Notater2) Spørg personalet |
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|  | **DAILY DATA day 1-14** |  |
|  | **Major protocol violations on this day** |  |
| MPV1 | Treatment with open-label systemic corticosteroids on this day? | SP-Resume -> MDA historik |
|  | **Life-supportive interventions** |  |
| D1 | Did the patient receive invasive mechanical ventilation on this day? | SP- Vurderingsskema -> resp |
| D2 | Did the patient receive infusion of vasopressors or inotropes for at least one hour on this day? | SP-Resume -> MDA historik |
| D3 | Did the patient receive renal replacement therapy on this day? | 1. SP-Vurderingsskema ’CRRT’
2. SP – Notater

3) SP – Resume – ’Dialyse og CRRT overblik’ |
|  | **Serious Adverse Reactions** |  |
| SAR1 | Clinically important gastrointestinal bleeding on this day? | Transfusion: SP-Resultater -> mere -> parakliniske -> blodbank -> transfusionshistorikBlødning: SP-Notat |
| SAR2 | New onset septic shock on this day? | Mistænkt infektion: SP- NotaterLaktat: SP-resultaterVasopressor: SP-resume -> MDA historik |
| SAR3 | Invasive fungal infection on this day? | 1) SP-Resultater2) SP-Resultater -> mere -> parakliniske systemer -> mikrobiologi |
| SAR4 | Anaphylactic reaction to IV hydrocortison? | SP – Notat |

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|  | **DISCHARGE AND READMISSION FORM** |  |
| 1 | Date/time | SP-Resume -> SP – Behandlingstidslinje |
| 2 | Discharged to | 1) SP-Resume -> SP – Behandlingstidslinje2) SP -> vis journal -> behandlingskontakter -> flytningshistorik |
| 3 | Date/time of possible readmission | 1) SP-Resume -> SP – Behandlingstidslinje |

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|  | **WITHDRAWAL FORM** |  |
| W1+2 | Date/time of withdrawal | SP-Notat |
| W3 | Reason for withdrawal | SP-Notat |
| W3a+b | Consent not given/further data registration | Samtykkeblanket |

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|  | **28 DAYS FOLLOW-UP** |  |
| FU1 | Date | eCRF |
| FU2 | Did the patient die within 28 days of follow-up? | 1) SP-åben journalen (kun hvis pt. er I reg H / reg S gives advarsel om at pt. er død. Hvis ikke:2) SP-Vis journal -> sundhedsjournalen  |
| FU2a | Date of death? | 1) SP-Header-> hold curser på pt-navn2) SP-Vis journal -> sundhedsjournalen |
|  | **Duration of life-support to day 28** |  |
| FU3 | How many days from day 15 – 28 did the patient receive invasive mechanical ventilation? | SP- Vurderingsskema -> resp |
| FU4 | How many days from day 15 – 28 did the patient receive vasopressors or inotropes? | SP-Resume -> MDA historik |
| FU5 | How many days from day 15 – 28 did the patient receive renal replacement therapy? | SP – Resume – ’Dialyse og CRRT overblik’ |
| FU6 | How many days from **randomisation** to day 28 did the patient receive ECMO therapy? | SP-forside -> fritekstsøgning : ecmo |

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|  | **90 DAYS FOLLOW-UP** |  |
| FU1 | Date | eCRF |
| FU2 | Did the patient die within 90 days of follow-up? | 1) SP-åben journalen (kun hvis pt. er I reg H / reg S gives advarsel om at pt. er død. Hvis ikke:2) SP-Vis journal -> sundhedsjournalen |
| FU2a | Date of death? | 1) SP-Header-> hold curser på pt-navn2) SP-Vis journal -> sundhedsjournalen |
|  | **Duration of life-support to day 90** |  |
| FU3 | How many days from day 29 – 90 did the patient receive invasive mechanical ventilation? | SP- Vurderingsskema -> resp |
| FU4 | How many days from day 29 – 90 did the patient receive vasopressors or inotropes? | SP-Resume -> MDA historik |
| FU5 | How many days from day 29 – 90 did the patient receive renal replacement therapy? | SP – Resume – ’Dialyse og CRRT overblik’ |
|  | **Length of hospital stay at day 90** |  |
| FU6 | Discharged alive from the hospital within 90 days? | 1) SP-Resume -> SP – Behandlingstidslinje2) SP -> vis journal -> behandlingskontakter -> flytningshistorik |
| FU6a | Date of hospital discharge (index admission) | SP -> vis journal -> behandlingskontakter -> flytningshistorik |

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|  | **1-year FOLLOW-UP FORM** |  |
| FU1 | Date | eCRF |
| FU2 | Was the patient dead on the date of follow-up? | 1) SP-åben journalen (kun hvis pt. er I reg H / reg S gives advarsel om at pt. er død. Hvis ikke:2) SP-Vis journal -> sundhedsjournalen |
| FU2a | Date of death? | 1) SP-Header-> hold curser på pt-navn2) SP-Vis journal -> sundhedsjournalen |
|  | **Quality of life at 1-year post-randomisation** |  |
| FU3 | Lost to HRQoL follow-up? | Spørgeskema |
| FU3a | Date of EQ-5D-5L and EQ-VAS interviews | Spørgeskema |
| FU5-10 | EQ-5D-5L and EQ-VAS score | Spørgeskema |
| FU11 | HRQoL follow-up conducted by proxy? | Spørgeskema |