**Kildedataliste (template)**

**Protokoltitel:** Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF).

**Afdeling:**

**Hospital:**

**Primær investigator:**

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| **Data** | **Primary data source** |
| Consent | Samtykke erklæring i eCRF (uploaded) eller i site master file på papir |
| **SCREENING FORM** | |
| National identification number |  |
| Sex |  |
| **INCLUSION CRITERIA** | |
| Is the patient ≥ 18 years old? |  |
| Is the patient admitted to or planned to be admitted to the ICU? |  |
| Is the patient clinical stable? (Clinical stable defined as MAP > 50 mmHg and maximum infusion of 0.20 microgram/kg/minute of noradrenaline and lactate < 4,0 mmol/L) |  |
| Cumulative fluid balance |  |
| Actual body weight |  |
| Height |  |
| Ideal body weight | Automatic calculation in eCRF |
| Fluid overload | Automatic calculation in eCRF |
| **EXCLUSION CRITERIA** | |
| Has the patient allergy towards furosemide or sulphonamides? |  |
| Has the patient known pre-hospitalisation advanced chronic kidney disease? |  |
| Does the patient receive ongoing renal replacement therapy? |  |
| Anuria for > 6 hours? |  |
| Does the patient have **life-threatening** bleeding? |  |
| Does the patient have acute burn injury of more than 10% of the body surface area leading to the present ICU admission? |  |
| Does the patient have severe dysnatremia? |  |
| Does the patient have severe hepatic failure? |  |
| Is the patient undergoing forced treatment? |  |
| Is the patient pregnant? (women ≤ 50 years of age) |  |
| Consent unobtainable according to national regulations? |  |
| **PATIENT** | |
| Name of the patient |  |
| Habitual plasma creatinine value |  |
| Habitual plasma creatinine value (calculated) | Automatic calculation |
| Patient’s race (in case of calculated habitual plasma creatinine) | Race er ikke nødvendigvis noteret i patient-journalen eller andre steder, da det generelt ikke har betydning for patientbehandlingen. Derfor kan race være dokumenteret i eCRF’en alene af inkluderende læge. |
| Highest plasma creatinine value within the last 24 hours prior to randomisation? |  |
| Diuresis the last 24 hours |  |

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| **SMS-ICU SCORE** | |
| Lowest systolic blood pressure within the last 24 hours prior to randomisation? |  |
| Use of vasopressors/inotropica |  |
| Did the patient receive acute surgery during current hospital admission? |  |
| Respiratory support |  |
| Metastatic cancer or haematological malignancy? |  |
| **STRATIFICATION VARIABLES** |  |
| Site, AKI, SMS-score | Automatisk generet i eCRF |

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| **BASELINE FORM** | |
| **GENERAL PATIENT INFORMATION** | |
| Hospital admission date? |  |
| ICU admission date and time? |  |
| Location before ICU admission? |  |
| Did the patient receive elective surgery during current admission prior to randomisation? |  |
| Does the patient have septic shock according to the Sepsis-3 criteria? |  |
| **CO-MORBIDITIES PRIOR TO ICU ADMISSION** | |
| Ischemic heart disease? |  |
| Chronic obstructive pulmonary disease? |  |
| Diabetes? |  |
| Stroke or neurodegenerative illness? |  |
| Is the patient in treatment with diuretics from before admittance to hospital? |  |
| Is the patient receiving habitual diuretics during the ICU stay? |  |
| Which groups of habitual diuretics is the patient receiving during the ICU stay? |  |
| COVID-19 positive? |  |

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| **DAY FORM** | |
| Date/time | eCRF |
| **FLUIDS AND TRIAL DRUG** |  |
| Cumulated fluid balance |  |
| Urinary output |  |
| Measured weight |  |
| Cumulative dose of trial drug |  |
| Reason for pausing trial drug (hvis cumulative dose of trial drug is 0 mL) |  |
| Plasma creatinine |  |
| Indication for a new estimate of fluid balance? |  |
| Reasons for new estimate of fluid overload |  |
| New estimate of fluid balance |  |
| **MAJOR PROTOCOL VIOLATIONS** | |
| Discontinuation of goal directed fluid removal for 2 days before a neutral fluid balance has been achieved? |  |
| Has the patient received the trail drug for 2 days despite fulfilling pausing criteria resulting in a negative cumulative fluid balance of < -750 mL? |  |
| Is extra furosemide administered without the presence of escape indications? |  |
| Administration of other diuretics? |  |
| Initiation of renal replacement therapy without the presence of escape indications? |  |
| Participants withdrawing or withdrawn form the intervention despite having fluid overload? |  |
| **CO-INTERVENTIONS** |  |
| Vasopressor/inotropes? |  |
| Invasive mechanical ventilation? |  |
| Use of escape renal replacement therapy and the reasons why. |  |
| Use of open label furosemide? |  |
| Use of resuscitation algorithm? |  |
| **SERIOUS ADVERSE EVENTS** |  |
| Cerebral ischemia? |  |
| Acute myocardial ischemia? |  |
| Intestinal ischemia? |  |
| Limb ischemia? |  |
| New episode of acute kidney injury stage 3? |  |
| Atrial fibrillation for the first time? |  |
| **SERIOUS ADVERSE REACTIONS** |  |
| Anaphylactic reaction? |  |
| General tonic-clonic seizures? |  |
| Severe electrolyte disturbance? |  |
| Agranulocytosis? |  |
| Aplastic anaemia? |  |
| Pancreatitis? |  |
| Circulatory collpase leading to cardiac arrest? |  |
| Steven Johnsosns syndrome? |  |
| Toxic epidermal necrolysis? |  |
| Hearing impairment/loss? |  |

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| **DISCHARGE AND READMISSION FORM** | |
| Date/time |  |
| Discharged to |  |
| Date/time of possible readmission |  |
| COVID-19 positive? |  |

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

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| **90 DAYS FOLLOW-UP** | |
| Date |  |
| Was the patient dead at 90 days follow-up? |  |
| Date of death (if relevant) |  |
| If discharged from hospital within 90 days: Date of discharge and additional admissions (if relevant) |  |

Investigator (navn): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dato: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_ Underskrift: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**VEJLEDNING**

**Kildedokument**

Kildedatalisten anvendes af Good Clinical Practice (GCP) monitorerne til at validere indtastede data. Kildedokumentet er det første sted data registreres. Der skal angives en kilde til samtlige data, der indsamles i CRF’en og henvisningerne skal opføres i kildedatalisten. Hvis flere kilder er mulige, skal alle angives i prioriteret rækkefølge, dvs. kilder der vægter højest hvis data i de forskellige kilder ikke er identiske placeres først.

**Eksempler på kildedokumenter, som kan være både elektroniske og fysiske dokumenter**

EKG-udskrift, elektronisk medicin-journal, eCRF, epikrise, journalkontinuationer, sygeplejenotater osv.

Beskriv kildedokumentet så specifikt som muligt.

**Udarbejdelse og opbevaring**

Kildedatalisten skal foreligge underskrevet af lokal investigator ved initieringsbesøget. Det kan være nødvendigt at revidere listen undervejs i forsøget. Alle underskrevne versioner af listen, skal arkiveres i site master file.