**Kildedataliste (sundhedsplatformen)**

**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 | SP – header |
| Sex | SP – header |
| **INCLUSION CRITERIA** | |
| Is the patient ≥ 18 years old? | SP – header |
| Is the patient admitted to or planned to be admitted to the ICU? | 1) SP – behandlingstidslinje  2) SP – notat |
| 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) | MAP: vurderingsskemaer  Noradrenaline: SP-MDA, SP-vurderingsskemaer, SP-notater,  Laktat: SP – resultatgennemgang |
| Cumulative fluid balance | SP – indgift/udskillelse |
| Actual body weight | SP – vurderingskema (ikke fra header) |
| Height | SP – vurderingsskema  SP – header |
| Ideal body weight | Automatic calculation in eCRF |
| Fluid overload | Automatic calculation in eCRF |
| **EXCLUSION CRITERIA** | |
| Has the patient allergy towards furosemide or sulphonamides? | SP – CAVE in header |
| Has the patient known pre-hospitalisation advanced chronic kidney disease? | SP – resultatgennemgang  SP – notater |
| Does the patient receive ongoing renal replacement therapy? | SP – notater  SP – vurderingsskema (CRRT Dialyse) |
| Anuria for > 6 hours? | SP – vurderingsskemaer (urogenitalt) |
| Does the patient have **life-threatening** bleeding? | SP – notater |
| Does the patient have acute burn injury of more than 10% of the body surface area leading to the present ICU admission? | SP – notater |
| Does the patient have severe dysnatremia? | SP – resultatgennemgang |
| Does the patient have severe hepatic failure? | SP – notater  SP – resultatgennemgang |
| Is the patient undergoing forced treatment? | SP – notater |
| Is the patient pregnant? (women ≤ 50 years of age) | SP – notater  SP – resultatgennemgang |
| Consent unobtainable according to national regulations? | SP – notater |
| **PATIENT** | |
| Name of the patient | SP – header |
| Habitual plasma creatinine value | SP – resultatgennemgang |
| Habitual plasma creatinine value (calculated) | Automatic calculation |
| Patient’s race (in case of calculated habitual plasma creatinine) | SP - notes (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? | SP – resultatgennemgang |
| Diuresis the last 24 hours | SP – vurderingsskemaer (urogenitalt eller indgift/udgift) |

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| **SMS-ICU SCORE** | |
| Lowest systolic blood pressure within the last 24 hours prior to randomisation? | SP – vurderingsskemaer (’cirk’) |
| Use of vasopressors/inotropica | SP – MDA  SP – tidslinje  SP - notater |
| Did the patient receive acute surgery during current hospital admission? | SP – notater  SP - behandlingstidslinjen |
| Respiratory support | SP – vurderingsskema (’Resp’) |
| Metastatic cancer or haematological malignancy? | SP – notater |
| **STRATIFICATION VARIABLES** |  |
| Site, AKI, SMS-score | Automatisk generet i eCRF |

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| **BASELINE FORM** | |
| **GENERAL PATIENT INFORMATION** | |
| Hospital admission date? | SP - behandlingstidslinje  SP – notater |
| ICU admission date and time? | SP – behandlingstidslinje |
| Location before ICU admission? | SP – behandlingstidslinje  SP – notater |
| Did the patient receive elective surgery during current admission prior to randomisation? | SP – notater |
| Does the patient have septic shock according to the Sepsis-3 criteria? | Infektion: SP – notater eller resultater (mikrobiologi MiBa)  Vasopressor: SP – MDA, SP – notater  Laktat: SP - resultatgennemgang |
| **CO-MORBIDITIES PRIOR TO ICU ADMISSION** | |
| Ischemic heart disease? | 1) SP – diagnoseliste  2) SP – notater |
| Chronic obstructive pulmonary disease? | 1) SP – diagnoseliste  2) SP – notater |
| Diabetes? | 1) SP – diagnoseliste  2) SP – notater |
| Stroke or neurodegenerative illness? | 1) SP – diagnoseliste  2) SP – notater |
| Is the patient in treatment with diuretics from before admittance to hospital? | SP – notater (ofte i AOP ved indlæggelse på hospitalet, men kan også være beskrevet i andre notater)  SP – MDA (her vil vanlig medicin kun figurere hvis en læge har trukket det over via FMK. Dette gøres oftest i forbindelse med indlæggelse på hospitalet) |
| Is the patient receiving habitual diuretics during the ICU stay? | SP - MDA |
| Which groups of habitual diuretics is the patient receiving during the ICU stay? | SP - MDA |
| COVID-19 positive? | SP - notater eller resultater (mikrobiologi MiBa) |

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

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| **DISCHARGE AND READMISSION FORM** | |
| Date/time | SP – behandlingstidslinje |
| Discharged to | SP – udskrivnings- / Flytnings-notat  SP - behandlingstidslinje |
| Date/time of possible readmission | SP – behandlingstidslinje |
| COVID-19 positive? | SP – resultatgennemgang (mikrobiologisk, MiBa) |

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

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| **90 DAYS FOLLOW-UP** | |
| Date | eCRF |
| Was the patient dead at 90 days follow-up? | SP – åben journalen – I tilfælde af død kommer der en advarsel om at patienten er død, |
| Date of death (if relevant) | SP – header – hold curser over pt-navn  SP - morsnotat |
| If discharged from hospital within 90 days: Date of discharge and additional admissions (if relevant) | SP – behandlingstidslinje |

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.