**Primary data source (template)**

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

**Department:**

**Hospital:**

**Primary investigator:**

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| **Data** | **Primary data source** |
| Consent |  |
| **SCREENING FORM** |
| National identification number |  |
| Sex |  |
| **INCLUSION CRITERIA** |
| Is the patient ≥ 18 years old? |  |
| Was the patient acutely 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? |  |
| Has the patient rhabdomyolysis with indication for forced diuresis? |  |
| Is the patient included in a trial where co-enrollment with GODIF is not allowed? | Co-enrollment list in site master file or [www.cric.nu/godif/](http://www.cric.nu/godif/) under trial documents |
| **PATIENT** |
| Name of the patient |  |
| Habitual plasma creatinine value |  |
| Habitual plasma creatinine value (calculated) | Automatic calculation in the eCRF |
| Patient’s race (in case of calculated habitual plasma creatinine) |  |
| 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 | Automatic generated in the 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**  |
| Trial drug has been stopped for 48 hours before neutral cumulative fluid balance has been achieved? |   |
| Trial drug has been administered/continued for 48 hours after the patient reached neutral fluid balance resulting in a negative cumulative fluid balance larger than -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? |  |
| **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 collapse 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 (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**INSTRUCTIONS**

**Source document**

The source data list is used by the Good Clinical Practice (GCP) monitors to validate entered data. The source document must describe the location where data is recorded. A source must be provided for all data collected in the CRF and the references must be entered in the source data list. If several sources are possible, all must be indicated in order of priority, ie. sources that have the highest weight if the data in the different sources are not identical are placed first.

**Examples of source documents, which can be both electronic and physical documents**

ECG transcript, electronic medicine dispensing program, eCRF, all kinds of notes from clinical staff, fluid chart, etc.

Describe the source document as specifically as possible.

**Preparation and storage**

The source data list must be signed by the local investigator at the initiation visit. It may be necessary to revise the list during the experiment. All signed versions of the list must be archived in the site master file.