**Kildedataliste**

**Protokoltitel:** The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial

**Afdeling:**

**Hospital:**

**Investigator:**

|  |  |
| --- | --- |
| **Data** | **Primary data source** |
| Consent | Samtykkeerklæring |
| **SCREENING FORM** |  |
| National identification number | SP – Header |
| **INCLUSION CRITERIA** |  |
| Age | SP – Header  |
| Admission or planed admission to ICU | 1) SP - Behandlingstidslinje2) SP – Notat |
| Septic shock according to the Sepsis-3 criteria? | Vasopressor/inotropika: 1) SP – MDA, 2) SP-NotaterLaktat: SP – ResultatgennemgangMistænkt infektion: SP- Notater |
| At least 1 L of IV fluid in the last 24-hours prior to screening? | SP – Notater SP-Indgift/udskillelse |
| **EXCLUSION CRITERIA** |  |
| Has the patient had septic shock for more than 12 hours at the time of screening? | Vasopressor: 1) SP – MDA, 2) SP-NotaterLaktat: SP – ResultatgennemgangMistænkt infektion: SP- Notater |
|  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? | SP – Notater |
|  Is the patient pregnant? | 1) SP – Notater2) SP- Resultatgennemgang |
|  Consent unobtainable according to national regulations? | SP – Notater |

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| **Data** | **Primary data source** |
| **STRATIFICATION VARIABLES** |  |
| Site | eCRF |
| Metastatic cancer or hematological malignancy? | 1) SP – Diagnoseliste2) SP - Notater |
| **BASELINE FORM** |  |
| **GENERAL PATIENT INFORMATION** |  |
| Sex | SP – Header |
| Date-of-birth | SP - Header |
| Hospital admission date? | 1) SP- Behandlingstidslinje2) SP – Notater |
| ICU admission date and time? | 1) SP – Behandlingstidslinje2) SP-Patientstation |
| Location before ICU admission? | 1) SP-Behandlingstidslinje2) SP - Notater |
| Focus of infection? | 1) SP – Notater2) SP-Diagnoseliste |
| **Co-morbidities** |  |
| Ischemic heart disease? | 1) SP – Diagnoseliste2) SP - Notater |
| Chronic hypertension? | 1) SP – Diagnoseliste2) SP – Notater3) SP – best.ord/MDA |
| Chronic renal replacement therapy? | SP – Notat SP- Diagnoseliste |
| **Blood values, interventions and vital parameters** |  |
| Weight | SP – Vurderingsskemaer IKKE SP-Header |
| Highest plasma lactate 3 hours prior to randomisation? | 1) SP – Resultatgennemgang2) SP-Vurderingsskemaer ’CIRK’ |
| Highest dose of noradrenaline 3 hours prior to randomisation?  | SP – MDASP-Vurderingsskemaer ‘CIRK’SP- Notater |
| Infused IV fluid volume 24 hours prior to randomisation? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Use of systemic corticosteroids 24 hours prior to randomisation? | SP – MDA |
| Highest plasma creatinine value 24 hours prior to randomisation? | SP- Resultatgennemgang |
| Use of acute renal replacement therapy 3 days prior to randomisation? | 1) SP- Vurderingsskema ‘CRRT Dialyse’2) SP- Notater3) SP- Resume – ’Dialyse og CRRT overblik’ |
| Habitual plasma creatinine value prior to current hospitalisation? | SP - Resultatgennemgang |
|  |  |
| **SMS-ICU** |  |
| Systolic blood pressure | SP – Vurderingsskema ‘Cirk’ |
| Vasopressors | SP – MDA SP- Vurderingsskemae ‘CIRK’ |
| Respiratory support | SP – Vurderingsskema ‘Resp’ |
| Renal replacement therapy | 1) SP – Vurderingsskema ’CRRT Dialyse’2) SP- Notater3) SP- Resume – ’Dialyse og CRRT overblik’ |
| Acute surgery | SP - NotaterSP-Behandlingstidslinje |
| **DAY FORM** |  |
| **Time span** |  |
| Date/time | eCRF |
| **Fluid input and output** |  |
|  IV crystalloids? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| IV fluid of other types? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| IV albumin? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| IV fluid with medication? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Enteral and parenteral nutrition? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Non-nutritional enteral/oral fluid? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Blood products? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Urinary output? | 1) SP – Indgift/udskillelse2) SP- Vurderingsskemaer ‘Indgift/udgift’ |
| Renal replacement therapy and volume of fluid removal? | 1) SP – Vurderingsskema ’CRRT Dialyse’2) SP- Notater3) SP- Resume – ’Dialyse og CRRT overblik’ |
| Other fluid losses? | SP – Indgift/udskillelse |
| **Major protocol violations** |  |
| Volume IV fluids given without one of the extenuating circumstances? | 1) SP – Notater2) SP – Indgift/udskillelse3) SP- Vurderingsskemaer ‘Indgift/udgift’  |
| **Co-interventions** |  |
| Vasopressor/inotropes? | SP – MDA |
| Systemic corticosteroids? | SP – MDA  |
| Invasive mechanical ventilation? | SP – Vurderingsskema ‘RESP’  |
| Renal replacement therapy? | 1) SP – Vurderingsskema ’CRRT Dialyse’2) SP- Notater3) SP- Resume – ’Dialyse og CRRT overblik’ |
| **OUTCOMES** |  |
| Kreatinine | SP - Resultatgennemgang |
| Cerebral ischemia? | 1) SP- Notater2) SP- resultatgennemgang ’Xeroviewer’ |
| Acute myocardial ischemia? | 1) SP – Notater2) SP- Resultatgennemgang ’Kardia’ |
| Intestinal ischemia? | SP - Notater |
| Limb ischemia? | SP - Notater |
| **SAR** |  |
| Anaphylactic reaction | SP - Notat |
| General tonic-clonic seizures | SP – Notat |
| Central pontine myelinolysis | SP – Notat |
| Hypernatremia | SP – NotatSP-Resultatgennemgang |
| Severe hyperchloremic acidosis | SP – NotatSP-Resultatgennemgang |
| Severe metabolic alkalosis | SP – NotatSP-Resultatgennemgang |
| **DISCHARGE AND READMISSION FORM** |  |
| Date/time | SP – Behandlingstidslinje |
| Discharged to | SP – Udskrivnings- / Flytnings-notat |
| Date/time of possible readmission | SP – Behandlingstidslinje  |
| **WITHDRAWAL FORM** |  |
| Date/time | eCRF |
| Reason | SP - Notat |
| Consent not given/further data registration | SP - Notat |
| **90 DAYS FOLLOW-UP** |  |
| Date | eCRF |
| If discharged from hospital within 90 days: Date of discharge and additional admissions | SP – Behandlingstidslinje  |
| Dead | LPR |

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.