

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 - Behandlingstidslinje 2) SP – Notat
Septic shock according to the Sepsis-3 criteria?	Vasopressor/inotropika: SP – MDA, SP-Notater Laktat: SP – Resultatgennemgang Mistænkt 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: SP – MDA, SP-Notater Laktat: SP – Resultatgennemgang Mistænkt 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?	SP – Notater 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 – Diagnoseliste 2) SP - Notater
BASELINE FORM	
GENERAL PATIENT INFORMATION	
Sex	SP – Header
Date-of-birth	SP - Header
Hospital admission date?	SP- Behandlingstidslinje SP – Notater
ICU admission date and time?	SP – Behandlingstidslinje
Location before ICU admission?	SP-Behandlingstidslinje SP - Notater
Focus of infection?	SP - Notater
Co-morbidities	
Ischemic heart disease?	1) SP – Diagnoseliste 2) SP - Notater
Chronic hypertension?	1) SP – Diagnoseliste 2) SP - Notater
Chronic renal replacement therapy?	SP – Notat SP- Diagnoseliste
Blood values, interventions and vital parameters	
Weight	SP – Vurderingsskemaer IKKE SP-Header

Highest plasma lactate within 3 hours of randomisation?	SP – Resultatgennemgang
Highest dose of noradrenaline within 3 hours of randomisation?	SP – MDA SP-Vurderingsskemaer 'CIRK' SP- Notater
Infused IV fluid volume within 24 hours of randomization?	SP – Indgift/udskillelse
Use of systemic corticosteroids within 24 hours of randomisation?	SP – MDA
Highest plasma creatinine value within 24 hours of randomisation?	SP- Resultatgennemgang
Use of acute renal replacement therapy within 3 days of randomisation?	1) SP- Vurderingsskema 'REN' 2) SP- Notater
Habitual plasma creatinine value prior to current hospitalization?	SP - Resultatgennemgang

SMS-ICU	
Systolic blood pressure	SP – Vurderingsskema 'Cirk'
Vasopressors	SP – MDA SP- Vurderingsskemaer 'CIRK'
Respiratory support	SP – Vurderingsskema 'Resp'
Renal replacement therapy	SP – Vurderingsskema 'CRRT'
Acute surgery	SP - Notater SP-Behandlingstidslinje
DAY FORM	
Time span	
Date/time	eCRF
Fluid input and output	
IV crystalloids?	SP – Indgift/udskillelse

IV fluid of other types?	SP – Indgift/udskillelse
IV albumin?	SP – Indgift/udskillelse
IV fluid with medication?	SP – Indgift/udskillelse
Enteral and parenteral nutrition?	SP – Indgift/udskillelse
Non-nutritional enteral/oral fluid?	SP – Indgift/udskillelse
Blood products?	SP – Indgift/udskillelse
Urinary output?	SP – Indgift/udskillelse
Renal replacement therapy and volume of fluid removal?	SP – Notater SP - Vurderingsskema 'REN'
Other fluid losses?	SP – Indgift/udskillelse
Major protocol violations	
Volume IV fluids given without one of the extenuating circumstances?	SP – Notater SP – Indgift/udskillelse
Co-interventions	
Vasopressor/inotropes?	SP – MDA
Systemic corticosteroids?	SP – MDA
Invasive mechanical ventilation?	SP – Vurderingsskema 'RESP'
Renal replacement therapy?	SP – Notater SP - Vurderingsskema 'REN'
OUTCOMES	
Kreatinine	SP - Resultatgennemgang
Cerebral ischemia?	SP- Notater
Acute myocardial ischemia?	SP - Notater
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 – Notat SP-Resultatgennemgang
Severe hyperchloremic acidosis	SP – Notat SP-Resultatgennemgang
Severe metabolic alkalosis	SP – Notat SP-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.