VA WEST HAVEN CSP530

ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)

Annotated form 9816565471 FORM 09 - RENAL REPLACEMENT THERAPY - EACH TREATMENT

Hospital | PatID | PatInits | Treatment Date (mm/dd/yy) | Treatment No. This Date

[ ][ ][ ] | [ ][ ][ ] | [ ][ ][ ] | [ ][ ] / [ ][ ] / [ ][ ] Date | [ ] TreatNo

A. Treatment Day (choose one only)

1. [ ][ ] PreRandCode Pre-randomization (code 00)

2. [ ][ ] StudyDay Study Day (code 01, 02, 03,...,28)

B. Time of day RRT started (military) TimeRRT [ ][ ][ ][ ]

ContinueRRT

1. If on continuous therapy, is it continued from previous day? ---------- ☐ Yes ☐ No

C. Selection of RRT Modality

1. Cardiovascular SOFA Score [ ] CardioSofaScore

2. Type of RRT (check one) TypeRRT

☐ Hemodialysis (complete section E)

☐ CVVHDF (complete section F)

☐ SLED (complete section E)

☐ Isolated Ultrafiltration (complete section D)

D. ISOLATED ULTRAFILTRATION

1. Indication for isolated ultrafiltration Edema

a. Severe Edema ---------- ☐ Yes ☐ No

Lungs

b. Lungs (check one) ---------- ☐ Clear ☐ Pulmonary Vascular Congestion

c. CVP ---------- CVP [ ][ ] mmHg CVPNA ☐ N/A*

d. Pulmonary Artery Pressure (systolic/diastolic) ---------- PASystolic [ ][ ][ ] / PADiastolic [ ][ ] mmHg ☐ N/A* PASystoDiastoNA

e. Pulmonary Capillary Occlusion Pressure ---------- PCOPress [ ][ ] mmHg ☐ N/A* PCOPressNA

f. Oxygenation ---- SaO SaO_2 [ ][ ][ ] % **OR** PaO_2 [ ][ ][ ] mmHg PaO

FiO FiO_2 [ ][ ][ ] % **OR** OxyFloRate Oxygen flow rate [ ][ ] liters/min

2. Duration of ultrafiltration ---- DuraUltraFiltHr [ ][ ] hours DuraUltraFiltlMin [ ][ ] minutes

3. Dialyzer (see Ops manual for codes) ---------- Dialyzer [ ][ ] mL/min

4. Blood flow rate ---------- BFR [ ][ ][ ]

5. Pre-treatment weight ---------- PreTreatWeight [ ][ ][ ].[ ] kg PreTreatWeightNA ☐ N/A*

6. Fluid removal ---------- FluidRemoval [ ][ ].[ ] L

*N/A means Not Available

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Date

E. HEMODIALYSIS or SLED

1. Dialyzer (see Ops Manual for codes) ---------- HemoDialyzer [ ][ ]

2. Actual duration of dialysis (hours and minutes) ---- DuraDialHr [ ][ ] hours [ ][ ] mins

3. Blood flow rate (average achieved) ---------- HemoBFR [ ][ ][ ] mL/min DuraDialMin

4. Dialysate flow rate ---------- HemoDFR [ ][ ][ ] mL/min

5. Pre-dialysis weight ---------- PreDialWeight [ ][ ][ ].[ ] kg ☐ N/A* PreDialWeightNA

6. Net fluid removal (based on ultrafiltration monitor and administered fluids) ---------- NetFluidRemove [ ][ ].[ ] L

7. Assessment of dialysis adequacy performed? ---------- Yes ☐ No ☐ PrePostDialBUN

NOTE: Pre-and Post-dialysis BUNs are to be collected and Kt/V calculated at least 3 times per week for first 2 weeks on study and at least once per week for the remainder of the time the patient is on the study therapy.

If yes, a. BUN at initiation of today's treatment ------ BUNInit [ ][ ][ ] mg/dL

b. BUN at termination of today's treatment ---- BUNTerm [ ][ ][ ] mg/dL

c. Calculated spKt/V ---------- SpKev [ ].[ ][ ]

8. Anticoagulation (choose one) HemoAnticoag HemoAnticoagDesc

☐ None ☐ Heparin ☐ Citrate ☐ Other, specify

9. Clotting of extracorporeal circuit requiring hemodialyzer repl HemoClotting ☐ Yes ☐ No

10. a. Blood pressure at initiation of treatment InitialSystolicBP [ ][ ][ ] / InitialDiastolicBP [ ][ ][ ]

b. Lowest documented blood pressure during treatment --- LowSystolicBP [ ][ ][ ] / LowDiastolicBP [ ][ ][ ]

F. CVVHDF

1. Hemodiafilter (see Ops Manual for codes) --------- Diafilter [ ][ ] CVVHDFDuraMin

2. Actual duration of therapy (hours and minutes) ---- CVVHDFDuraHr [ ][ ] hours [ ][ ] mins

3. Blood flow rate (prescribed) ---- CVVHDFBFR [ ][ ][ ] mL/min

4. Dialysate flow rate (prescribed) ---- a. [ ][ ][ ][ ] mL/hour CVVHDFDFR

b. Dialysate code [ ] (see Ops Manual) Dialysate

5. Replacement fluid administration rate (prescribed) --- a. [ ][ ][ ][ ] mL/hour RFAR

b. Replacement Fluid Code [ ] (see Ops Manual) ReplaceFluidCode

*N/A means Not Available

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F. CVVHDF (cont'd)

Date

6. Ultrafiltration rate (prescribed) ---------- UltraFiltRate ____ mL/hour

7. 24-hour effluent volume (actual) ---- EffluentVolume ____.__ L

8. Anticoagulation (choose one) CVVHDFAnticoag

☐ None ☐ Heparin ☐ Citrate ☐ Other, specify CVVHDFAnticoagDesc

9. Clotting of extracorporeal circuit requiring hemodiafilter r CVVHDFClotting ☐ Yes ☐ No

10. Number of hemodiafilters used during this 24-hour trea CVVHDFDiafilters __

G. COMPLICATIONS OF THERAPY (complete for all types of RRT)

	No	Yes	If Yes, check if it is an SAE*
1. Anaphylactic reaction to dialyzer ("first-use" reaction) ---------- Anaphylactic	☐	☐	☐ AnaphylacticSAE
2. Hypotension requiring initiation of pressor support during treatment HypoPresSupp	☐	☐	☐ HypoPressSuppSAE
3. Hypotension requiring discontinuation of therapy ---------- HypoDisco	☐	☐	☐ HypoDiscoSAE
4. Hypotension requiring other intervention ---------- HypoOther	☐	☐	☐ HypoOtherSAE
5. Air embolism ---------- AirEmbolism	☐	☐	☐ AirEmbolismSAE
6. Bleeding (e.g., due to system disconnection or dialyzer rupture) ---------- Bleeding	☐	☐	☐ BleedingSAE
7. New onset of serious arrythmia requiring discontinuation of therapy (e.g., rapid supraventricular tachycardia with hypotension, ventricular tachycardia) Arrythmia	☐	☐	☐ ArrythmiaSAE
8. Iatrogenic fluid and/or electrolyte imbalances ---------- Iatrogenic	☐	☐	☐ IatrogenicSAE
a. If yes, type of imbalance (see OPs Manual) __ IatrogenicType			
9. Seizures ---------- Seizures	☐	☐	☐ SeizuresSAE
10. Other ---------- OtherComplicat	☐	☐	☐ OtherComplicatSAE

Specify: OtherComplicatDesc1

OtherComplicatDesc2

NOTE: *IF ANY COMPLICATIONS HAVE OCCURRED THAT ARE BOTH SERIOUS AND TREATMENT-RELATED, PLEASE FILL OUT A SEPARATE SERIOUS ADVERSE EVENT FORM (Form 16) FOR EACH.

StaffInits

FormDate __/__/__ (mm/dd/yy) ___