Annotated form 7046256437

VA WEST HAVEN CSP 530
ACUTE RENAL FAILURE TRIAL NETWORK (ATN STUDY)
FORM 01 - SCREENING/ELIGIBILITY

Hospital | PatID | PatInits | Date (mm/dd/yy)

A. INCLUSION CRITERIA (To randomize the patient, items 1-6 must all be YES)

1. Acute renal failure clinically consistent with a diagnosis of ATN defined as condition (a) plus either condition (b) or (c) below ---------- ARF Yes ☐ No ☐

a. Clinical setting of acute ischemic or nephrotoxic injury ---------- IschemNeph Yes ☐ No ☐

b. An increase in serum creatinine of ≥ 2 mg/dL for males or ≥ 1.5 mg/dL for females over a period of ≤ 4 days ---------- IncreaseCreat Yes ☐ No ☐

1. Gender ---------- Gender male ☐ female ☐

2. Lowest serum creatinine within 4 days prior to screening ---------- BaselineCreat ___.___ mg/dL

date obtained ---------- BaselineCreatDate ___/___/___ mm/dd/yy

No value available ---------- NoBaselineCreat ☐

3. Serum creatinine at screening ---------- ScreenCreat ___.___ mg/dL

date obtained ---------- ScreenCreatDate ___/___/___ mm/dd/yy

4. Date of onset of acute renal failure ---------- ARFonsetDate ___/___/___ mm/dd/yy

c. Oliguria (average urine output < 20 mL/hour for > 24 hours) ---------- Oliguric Yes ☐ No ☐

1. 24-hour urine volume ---------- UrineVol24hr _____ mL

2. Clinical need for renal replacement therapy ---------- ClinRenalReplace Yes ☐ No ☐

3. Receiving care in critical care unit (e.g., ICU, MICU, SICU, CTICU) ---------- CCU Yes ☐ No ☐

a. If yes, check one CCUType

☐ MICU ☐ SICU ☐ CCU ☐ CTICU ☐ Trauma ☐ Mixed ☐ Other

THIS FORM MUST BE COMPLETED FOR ALL SCREENED PATIENTS

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NonRenalFail

4. One non-renal organ failure or sepsis; i.e., 1 or more of conditions a-f below is satisfied ☐ Yes ☐ No

PaO2FiO2

a. $PaO_2/FiO_2 \leq 300$ mmHg ---------- Yes ☐ No ☐

If yes, enter values

PaO_2 mmHg; ___ PaO2

FiO_2 ___ . ___ FiO2

PlateletsLow

b. Platelet count $\leq 100{,}000/mm^3$ ---------- Yes ☐ No ☐

If yes, enter value ___,___ $/mm^3$ Platelets

c. Bilirubin ≥ 2.0 mg/dL ---------- Yes ☐ No ☐ BilirubinHigh

If yes, enter value ___ . ___ mg/dL Bilirubin

d. Hypotension requiring pressor support for greater than 1 hour ---------- Yes ☐ No ☐ Hypotension

e. Glasgow Coma Scale ≤ 12 ---------- Yes ☐ No ☐ GlasgowScale

i. Patient is on sedation? ---------- Yes ☐ No ☐ Sedation

ii. Best Eye Response (check one):

EyeResponse

☐ No eye opening (1)
☐ Eye opening to pain (2)
☐ Eye opening to verbal command (3)
☐ Eyes open spontaneously (4)

iii. Best Motor Response (check one):

MotorResponse

☐ No motor response (1)
☐ Extension to pain (2)
☐ Flexion to pain (3)
☐ Withdrawal from pain (4)
☐ Localizes pain (5)
☐ Obeys commands (6)

iv. Best Verbal Response (check one)

VerbalResponse

a. Non-Intubated
☐ No verbal response (1)
☐ Incomprehensible sounds (2)
☐ Inappropriate words (3)
☐ Converses/Confused (4)
☐ Converses/Orientated (5)

b. Intubated
☐ Generally unresponsive (1)
☐ Questionable ability to talk (3)
☐ Seems able to talk (5)

OverallScore

v. Record overall score (sum of items ii through iv above) ___

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f. Sepsis defined as proven or suspected infection associated with one or more organ failures. Sepsis ---------- Yes ☐ No ☐

If yes,

1. Proven infection ---------- ProvenInfection Yes ☐ No ☐

2. Suspected infection ---------- SuspectedInfection Yes ☐ No ☐

3. Site of infection (see Operations manual) ---------- SiteInfection ☐☐

	Yes	No
5. Age ≥ 18 years ---------- Age	☐	☐
6. Informed consent signed? ---------- Consent	☐	☐

a. If yes, who signed informed consent (check one)? ---- SignedConsent ☐ Patient ☐ Surrogate

If surrogate signed, be sure to complete Section C of this form.

b. If no, (check one). ------ RefusedConsent ☐ Patient refused ☐ Surrogate refused ☐ Surrogate not available

B. EXCLUSION CRITERIA (To randomize the patient, items 1-15 must all be NO)

	Yes	No
1. Pre-Morbid serum creatinine >2mg/dL (males) or >1.5 mg/dL (females) BaselineCreatEx	☐	☐

a. Enter pre-morbid serum creatinine ------- ☐☐.☐ mg/dL PreMorbidCreat

b. Date obtained PreMorbidCreatDate ☐☐ / ☐☐ / ☐☐ mm/dd/yy

c. No value available ------- ☐ PreMorbidCreatNA

	Yes	No
2. Acute renal failure primarily due to an etiology other than ATN ---------- ATNEx	☐	☐

If yes,

a. Etiology code (see Ops Manual) --------- ☐☐ EtiologyCode

	Yes	No
3. More than 72 hours since BOTH of the following conditions were met. BothCondMet	☐	☐

a. Fulfilled definition of ARF.

1. Date definition of ARF first met ------ ARFDate ☐☐ / ☐☐ / ☐☐ mm/dd/yy

b. BUN > 100mg/dL

1. BUN at time of screening ---------- ☐☐☐ mg/dL ScreeningBUN

2. BUN 3 days prior to screening ---------- ☐☐☐ mg/dL ThreeDayBUN

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HemoDialysisEx	Yes	No
4. More than one hemodialysis treatment or longer than 24 hours since starting CRRT	☐	☐
5. Prior kidney transplant — KidneyTransplant	☐	☐
6. Patient pregnant — Pregnant	☐	☐
7. Patient is a prisoner — Prisoner	☐	☐
8. Pre-morbid weight > 128.5 kg — PreMorWeight	☐	☐
a. enter pre-morbid weight kg ___.___ PreMorWeightValue		
9. Non-candidacy for acute renal replacement therapy — NonCandARRT	☐	☐
10. Moribund state — MoribundState	☐	☐
11. Patient not expected to survive 28 days because of an irreversible chronic medical condition — Survival	☐	☐
12. Comfort-measures-only status — ComfortMeasure	☐	☐
13. Participation in a concurrent interventional study — ConcurrentStudy	☐	☐
14. Patient/Surrogate refusal — PatSurRefusal	☐	☐
15. Physician refusal — PhysRefusal	☐	☐

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C. THIS SECTION TO BE COMPLETED IF CONSENT IS BEING PROVIDED BY A SURROGATE

1. Patient deemed by 2 physicians to be unable to provide informed consent ---- Yes ☐ No ☐
   If no, surrogate consent cannot be used. Skip to Section E.
   If yes, complete remainder of this section.

PatUnableConsent

2. Name of person who signed informed consent

First Name Fname | MI | Last Name Lname

MI

3. Relationship of person who signed informed consent to patient (check one)
   ☐ Spouse/Partner ☐ Parent ☐ Sibling
   ☐ Child ☐ Friend ☐ Other relative Relation
   ☐ Other, specify: RelationDesc

4. Basis for using person named in item 2 above as surrogate (check one)
   ☐ Court-approved legal guardian Surrogate
   ☐ Durable power of attorney for healthcare
   ☐ Next of kin SurrogateDesc
   ☐ Other, specify:

Eligible

D. IS THIS PATIENT ELIGIBLE FOR RANDOMIZATION?

Yes ☐ No ☐

If yes, Complete Randomization Form (Form 03)

StaffInits

Date of Form Completion (mm/dd/yy) FormDate

Staff Initials