Prevent Cardiac Surgery Associated Acute Kidney Injury Trial (Prevent CSA-AKI Trial)

Efficacy of Mitochondrial directed therapy in prevention of cardiac surgery associated acute kidney injury

NCR224635 Data Dictionary

19-Feb-2024

A -Demographics

1- Date of admission
2- Surgery start date/time
3- Surgery end date/time
4- ICU admission date/time
5- ICU discharge date/time
6- Hospital discharge date/time
7- Hospital discharge date/time
8- Readmission to ICU date #1
9- Readmission to ICU date #2
10-Readmission to ICU date #3
11-Age on admission
12-Sex
    a. Male
    b. Female
13-Weight on admission
14-Race
    a. Asian
    b. Black
    c. White
    d. American Indian or Alaska Native
    e. Native Hawaiian or Another Pacific Islander
    f. Other
15-Ethnicity
    a. Hispanic
    b. Non-Hispanic
16-BMI on admission
17-H/o of cancer (type)
    a. Free text
18-H/o of systolic heart failure (options below)
    a. Acute
    b. Chronic
    c. Acute on chronic
19-H/o of diastolic heart failure (options below)
    a. Acute
    b. Chronic
    c. Acute on chronic
20-History of combined HF (systolic and diastolic) (18 and 19 cannot be yes if 20 is yes)
21-EF (%)
22-History of CAD

23-Valvular heart disease (valve)
   a. Aortic Valve disease
   b. Mitral Valve disease
   c. Tricuspid Valve disease
   d. Pulmonic Valve disease
24-COPD
25-DM
   a. Type I
   b. Type II
26-HTN
27-CKD stage III A
28-H/o of Atrial fibrillation
29-H/o Stroke
30-H/o of hypothyroidism
31-H/o of liver Cirrhosis
32-H/o of transplant (type – free text)
33-Immunosuppression
34-H/o of autoimmune disease
35-H/o of HIV

B- Surgery & Cardiac devices :

1-Typer of surgery :
- Single valve
- >1 valve
- CABG
- Combined CABG and $\geqslant 1$ valve
- Other

2-Cardiopulmonary bypass details:
- Skin incision start date/time
- Skin incision stop date/time
- Aortic cross clamp time (minutes)
- Cardio Pulmonary Bypass time (minutes)
- Lowest hematocrit % recorded in the OR
- Episode of MAP <50
- Episode of MAP < 50 for > 15 consecutive minutes

3- Cardiac devices (start and stop) :
- Impella (2.5 Vs 5)
- IABP
- ECMO (VA vs VV vs VAV)
- LVAD

C- New Diagnosis during admission:

- New A fib
- $\geqslant 2$ Sustained V tach episodes
- Bradycardia
- Complete heart block
- Cardiac arrest
- New pacemaker
- Pericarditis
- Pericardial effusion
- EF (changes in EF %)
- Cardiac tamponade
- Stroke
    - Hemorrhagic/location (free text for location)
    - Embolic/territory (free text for territory)
- Perioperative MI
- Graft occlusion
- Sepsis & source (yes/no; free text for source)
- Return to OR #1
    - Date
    - Reason (free text)
- Return to OR #2
    - Date
    - Reason (free text)
- Return to OR #3
    - Date
    - Reason (free text)
- Return to OR #4
    - Date
    - Reason (free text)
- Return to OR #5
    - Date
    - Reason (free text)
- Presence of bacteremia (source)
- Digit ischemia
- Intestinal /bowel/mesenteric ischemia
- Bleeding (location as free text)

D - Home Medications (all as yes/no)

- ACE I & ARB: Lisinopril, Enalapril, Captopril, losartan, Valsartan, Entresto
- Other Anti hypertensives: amlodipine, nifedipine, hydralazine, clonidine, imdur, doxazosine
- SGLT inhibitors: Empagliflozin, dapagliflozin, canagliflozin, ertugliflozin
- MRA: Spironolactone, Eplerenone
- Diuertics: hydrochlorothiazide, furosemide, Torsemide, bumetanide, metolazone, chlorothiazide
- Betablockers : Sotalol • Labetalol • Metoprolol. Atenolol • Bisoprolol • Carvedilol, Nadolol • Nebivolol
- Other AV node blocker: Amiodarone Digoxin, Diltiazem, Disopyramide, Dofetilide, Dronedarone, Flecainide, Propafenone, Quinidine sulfate, Verapamil

E- ICU medications (start and stop dates of the meds below, repeat entry as needed only if stopped $\geqslant$ 1 day)

- Pressor (Epi, NE, Neo, Vaso, ATII)
- Milrinone
- Dobutamine
- Diuertics: hydrochlorothiazide, furosemide, Torsemide, bumetanide, metolazone, chlorothiazide, spironolactone, eplerenone
- Hypertension meds: Amlodipine, nifedipine, hydralazine, clonidine, imdur, doxazosin
- BB: Sotalol, Labetalol, Metoprolol, Atenolol, Bisoprolol, Carvedilol, Nebivolol
- ACE I & ARB : Lisinopril, Enalapril, Captopril, losartan, Valsartan, Entresto
- SGLT inhibitors: Empagliflozin, dapagliflozin, canagliflozin, ertugliflozin)
- Other AV node blocker: Amiodarone, Digoxin, Diltiazem , Verapamil
- Dexmedetomidine

F. General Labs:

One set prior to OR and daily during admission if availble

- (Hemoglobin, Hematocrit, WBC, Platelets, BUN, Creatinine, eGFR , Bicarbonate, ALT, AST, bilirubin, Albumin, Magnesium, Potassium, sodium, Blood sugar , calcium, BNP, TSH, trop, lactic acid, INR.
- ABG (Ph, Pco2, Po2, Fio2)
- UA : proteinuria
- Urine protein creatinine ratio
- Urine albumin

G. Special labs (NIH):

- Serum and urinary levels of CoQ10, glutathione, serum and Urinary mtDNA

1st samples in the week prior to surgery

2nd sample in Day 0; the day of surgery

3rd sample in Day 1; the day after surgery

H. Clinical

1- Vitals:

- Prior to surgery : Heart rate , MAP, saturation
- Recording daily MAP, HR, Sat: (Mode: most common number for the day)
    - Number of Episodes of MAP <50
    - Number of episode of MAP < 50 for > 15 consecutive minutes

2- Respiratory: level of support daily including day prior to surgery (report only the final modality and amount of O2 support for each day)

- RA
- Nasal cannula
- HFNC
- BiPAP/ CPAP
- Vent
    - Mode
    - PEEP
    - Fio2
    - RR
    - start and stop date

3- Renal Replacement Therapy (RRT)

- CRRT (CVVH or CVVHD), start date, stop date
- Hemodialysis start and stop date

4- Volume status:

Daily Ins
Daily out
Daily Chest tube drainage
Daily urine output

5- Adverse events:

- Nausea
- Vomiting
- Diarrhea
- Rash
- Loss of appetite
- Other (free text)

I- evaluations/ calculations within 28 & 90 days:

- Apache & Sofa score calculation during ICU stay
- AKI stage
- AKD and CKD
- RRT dependence
- RRT free days
- Ventilator free days
- Death
- MAKE within 30 & 90 days
- Readmission (number/ dates/ reasons)

J. Definitions:

- AKI is defined as 2012 KDIGO guideline •Increase in SCr by equal or more than 0.3 mg per dl (equal or more than 26.5 µmol per l) within 48 hours; or •Increase in SCr to equal or more than 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or •Urine volume less than 0.5 ml per kg per h for 6 hours

- RRT dependence defined by the receipt of any form of RRT within + or - 14 days of the 90- day time point following randomization.

- RRT free days as the number of days between s from RRT and day 28 after study

Ventilator free days as the number of days between successful weaning from mechanical ventilation and day 28 after study enrollment

- Ventilator-free day is defined as the receipt of less than 2 hours of invasive or noninvasive ventilation within a 24-hour period.

- Shock-free days defined as less than 2 hours of receipt of any vasoactive therapy provided by continuous infusion within a 24-hour period.

-Make within 30 & 90 days (major adverse kidney events) defined by 1 or more of the following:

- In hospital mortality
- Death prior to discharge
- New receipt of RRT (any modality prior to hospital discharge)

Persistent renal dysfunction (final Creatinine before discharge $\geqslant$ 200% of the baseline Cr value in a patient not know to have previously received RRT

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NCR224635 Statistical Analysis Plan