

**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  $\geq 1$  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
- $\geq 2$  Sustained V tach episodes
- Bradycardia
- Complete heart block
- Cardiac arrest

- New pacemaker
- Pericarditis
- Pericardial effusion
- EF (changes in EF %)
- Cardiac tamponade
- Stroke
  - o Hemorrhagic/location (free text for location)
  - o Embolic/territory (free text for territory)
- Perioperative MI
- Graft occlusion
- Sepsis & source (yes/no; free text for source)
- Return to OR #1
  - o Date
  - o Reason (free text)
- Return to OR #2
  - o Date
  - o Reason (free text)
- Return to OR #3
  - o Date
  - o Reason (free text)
- Return to OR #4
  - o Date
  - o Reason (free text)
- Return to OR #5
  - o Date
  - o 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
- Diuretics: 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 $\geq 1$ day)**

- Pressor (Epi, NE, Neo, Vaso, ATII)
- Milrinone
- Dobutamine
- Diuretics: 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 available

- (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, Pco<sub>2</sub>, Po<sub>2</sub>, Fio<sub>2</sub>)
- UA : proteinuria
- Urine protein creatinine ratio
- Urine albumin

## **G. Special labs (NIH):**

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

1<sup>st</sup> samples in the week prior to surgery

2<sup>nd</sup> sample in Day 0; the day of surgery

3<sup>rd</sup> 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)
  - o Number of Episodes of MAP <50
  - o 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
  - o Mode
  - o PEEP
  - o Fio2
  - o RR
  - o 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  $\mu$ mol 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  $\geq 200\%$  of the baseline Cr value in a patient not known to have previously received RRT