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Prediction of acute kidney injury after cardiac surgery

Submission date 22/03/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/03/2017	**Overall study status** Completed	
Last Edited 16/05/2023	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Acute kidney injury (AKI) occurs when the kidneys suddenly stop working properly. It can cause complete kidney failure which is a very serious condition that can lead to death. It usually occurs after complications from illness or surgeries. AKI occurs in an estimated 36% of patients after a cardiac (heart) surgery. Therefore, people undergoing cardiac surgery are at a higher risk of AKI. However, it is hard to accurately predict the risk of AKI. There are tests that can evaluate renal function (how well the kidney works) by measuring creatinine levels in the kidneys (a type of waste that needs to be filtered by the kidneys to be then eliminated by urine (peeing)). This type of test could be used to see if there are indicators for risk of future AKI. The aim of this study is to examine kidney function prior to surgery is able to predict risk for AKI after surgery.

Who can participate?
Adults over the age of 18 who are undergoing elective cardiac surgery.

What does the study involve?
Participants undergo a kidney stress test prior to their elective cardiac surgery. This test takes seven hours and includes five measurements of serum creatinine (blood samples) and five one-hour urine samples in order to estimate creatinine levels. Participants then have their surgery and are followed up for seven days through daily blood tests to assess creatinine blood levels and by monitoring their urine levels. Three months after surgery, participants undergo another kidney stress test to evaluate renal function.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
San Bortolo Hospital (Italy)

When is the study starting and how long is it expected to run for?
April 2014 to February 2016

Who is funding the study?
San Bortolo Hospital (Italy)

Who is the main contact?
Dr Faeq Husain-Syed
faeqhusain@yahoo.de

Contact information

Type(s)
Scientific

Contact name
Dr Faeq Husain-Syed

ORCID ID
http://orcid.org/0000-0001-6742-5052

Contact details
San Bortolo Hospital
Viale Ferdinando Rodolfi
37
Vicenza
Italy
36100
+39 (0)444 753650
faeqhusain@yahoo.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03092947

Secondary identifying numbers
n63/14

Study information

Scientific Title
Use of preoperative renal function reserve to predict risk of acute kidney injury after cardiac surgery

Study objectives
The aim of this study is to see whether preoperative renal functional reserve predicts risk for acute kidney injury after cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Province Vicenza Italy, 20/08/2014, ref: n63/14

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files (in Italian)

Health condition(s) or problem(s) studied
Acute kidney injury after cardiac surgery

Interventions
Participants with normal glomerular filtration rates who are undergoing an elective cardiac surgery are included in this study. Participants undergo a preoperative kidney stress test using high oral protein loads. This is then repeated three months after surgery. The kidney stress test takes seven hours and includes five measurements of serum creatinine and five one-hour urine collection in order to estimate creatinine clearance.

Participants are followed for occurrence of postoperative acute kidney injury (AKI) for seven days after the surgery through daily serum creatinine blood tests and hourly urine output measurements according to the Acute Kidney Injury Guidelines of Kidney Disease Improving Global Outcomes (KDIGO).

Urine samples are taken from participants prior to surgery, thirty minutes after the cardiac bypass, at admission to the intensive care unit, at four, 12 and 24 hours after surgery and when participants are discharged from the hospital in order to examine urinary biomarkers.

Renal function is measured three months after surgery by repeating the kidney stress test.

Intervention Type
Other

Primary outcome measure

1. Renal functional reserve (RFR) is measured using a high oral protein load kidney stress test at baeline (before cardiac surgery) and three months after surgery
2. Acute kidney injury is measured using KDIGO criteria seven days after surgery

Secondary outcome measures
1. Occurrence of acute kidney injury impact the RFR is measured using Kidney Disease Improving Global Outcomes criteria at three months after surgery
2. Urinary biomarkers (TIMP-2 and IGFBP7) to predict loss of RFR are measured using urine samples at basline, 30 minutes after initiation of cardiopulmonary bypass, at intensive care unit admission, four, 12 and 24 hours after surgery and at hospital discharge

Overall study start date
01/04/2014

Completion date
26/02/2016

Eligibility

Key inclusion criteria
1. Older than 18 years
2. Undergoing elective cardiac surgery
3. Signed informed consent forms

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Pregnancy
2. Chronic kidney disease ≥ stage III
3. Solitary kidney
4. Diabetes mellitus type 1
5. Recent cardiac arrest
6. Liver failure or cirrhosis
7. Total parenteral nutrition
8. Hemoglobin <11 g/dl
9. Sepsis

10. History of malabsorption, chronic inflammatory bowel disease, short bowel, or pancreatic insufficiency
11. Transplant donor or recipient
12. Active autoimmune disease with renal involvement
13. Rhabdomyolysis
14. Prostate hypertrophy with International Prostate Symptom Score ≥20
15. Neoplasm

Date of first enrolment
03/11/2014

Date of final enrolment
29/10/2015

Locations

Countries of recruitment
Italy

Study participating centre
San Bortolo Hospital, Department of Cardiac Surgery
Via Rodolfi 37
Vicenza
Italy
36100

Sponsor information

Organisation
International Renal Research Institute

Sponsor details
San Bortolo Hospital
Department of Nephrology
Dialysis and Transplantation
Viale Ferdinando Rodolfi
37
Vicenza
Italy
36100
+39 (0)444 753650
cronco@goldnet.it

Sponsor type
Research organisation

Website
http://www.irriv.com

ROR
https://ror.org/053q96737

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
San Bortolo Hospital Italy

Results and Publications

Publication and dissemination plan
It is planned for publication in a high-impact peer reviewed journal.

Intention to publish date
23/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Faeq Husain-Syed at faeqhusain@yahoo.de

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		22/03/2017	06/04/2017	No	Yes
Participant information sheet		22/03/2017	06/04/2017	No	Yes
Participant information sheet		22/03/2017	06/04/2017	No	Yes
Results article	extended follow-up results	01/02/2019		Yes	No
Results article	results	31/01/2018	16/05/2023	Yes	No