Prediction of acute kidney injury after cardiac surgery

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

https://orcid.org/0000-0001-6742-5052

Contact details

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

Additional identifiers

ClinicalTrials.gov (NCT)

NCT03092947

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

https://ror.org/053q96737

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

San Bortolo Hospital Italy

Results and Publications

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 extended follow-up results	Date created Date added Peer reviewed? Patient-facing?			
Results article		01/02/2019	Yes	No	
Results article	results	31/01/2018 16/05/202	23 Yes	No	
Participant information sheet		22/03/2017 06/04/20	17 No	Yes	
Participant information sheet		22/03/2017 06/04/20	17 No	Yes	

Participant information sheet22/03/201706/04/2017 NoYesParticipant information sheetParticipant information sheet11/11/202511/11/2025 NoYes