ISRCTN95031194 https://doi.org/10.1186/ISRCTN95031194

Kidney injury after major surgery

Submission date	Recruitment status	[_] Prospectively registered
05/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/12/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2019	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute kidney injury (AKI) is sudden and severe damage to the kidneys that stops them working properly. AKI is a common complication for patients who are having major surgery, affecting as many as one in five people. In many cases, the decrease in kidney function does not last for long and so the problem could resolve itself without the doctor or the patient being aware of it. For this reason, it is often missed as the problem can only really be identified using specific medical tests. Recent studies have shown however, that patients who experience even mild AKI are likely to have longer hospital stays and have a greater chance of dying within the first few weeks after surgery. Importantly, as patients recover, kidney blood tests often return to normal even if the kidneys have been permanently damaged. These patients may be at risk of chronic (long-term) kidney disease over time, increasing their risk of severe heart disease, high blood pressure and permanent kidney failure needing dialysis. The aim of this study is to find out how common AKI is after major surgery and its long-term consequences for patients' kidney function, general health and well-being.

Who can participate?
Adults over 45 years of age who are undergoing major surgery (except heart surgery) by choice.

What does the study involve?
Patients having major surgery who have agreed to take part in the study have blood and urine samples taken before their operation in order to test for signs of any long-term kidney problems (chronic kidney disease). These samples are also taken 1, 3, 5 and 7 days after surgery, in order to test for signs of any new kidney problems (acute kidney injury). Patients who have been identified as suffering from chronic kidney disease (CKD) at the start of the study, those suffering from acute kidney injury (AKI) as well as randomly selected patients with normal kidney function are invited for follow up appointments at 30 and 365 days after surgery. At these appointments, further blood and urine samples are taken as well as having their glomerular filtration rate measured (a medical test where a substance is injected into the blood to measure how quickly the kidneys manage to remove it from the body (through urine production)).

What are the possible benefits and risks of participating?
Patients taking part in the study may benefit from more detailed healthcare screening and monitoring after they are discharged from hospital. There is a risk of bruising, pain and

discomfort from the blood testing. Also, participants may have to attend extra hospital appointments for monitoring, which could be an inconvenience.

Where is the study run from?
The Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

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Public

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Scientific

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Additional identifiers

Protocol serial number
19188

Study information

Scientific Title
Observational study of the long term outcomes of acute Kidney Injury after Major Surgery

Acronym
KIMS

Study objectives
The aim of this study is to determine how common acute kidney injury is after major surgery and its long-term consequences for patients' kidney function, general health and well-being.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 26/05/2015, ref: 15/EM/0222

Primary study design
Observational

Study design
Single-centre observational cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute kidney injury

Interventions
Patients will be approached for consent pre-operatively either in the pre-assessment clinic or on the day of surgery according to the inclusion and exclusion criteria. Blood samples (approximately 20ml) and urine are collected pre-operatively and on days 1, 3, 5 and 7 after surgery while in hospital. Patients with a diagnosis of peri-operative acute kidney injury (defined as a serum creatinine rise by >26µmol/L within 48h or x1.5 fold over baseline in over <7days) or baseline chronic kidney disease (defined by eGFR <60ml/min/1.73m2 on pre-operative blood tests) as well as randomly selected controls without AKI or CKD (approximately 1 in 8) will be invited back for follow-up renal functional assessment at 90 and 365 days after surgery (+/- 2 weeks). This will involve blood (approximately 20ml) and urine samples as well as an iohexol GFR measurement (a gold standard measure of renal function). This involves a 5ml injection of a non-toxic contrast media (iohexol) that is rapidly excreted in the kidneys and fingerpick blood samples (like a blood sugar test) at hourly intervals after the injection for a total of 2-5 time-points. At these appointment we will also ask questions on general health and physical activity and perform physical examination and vital signs. Of the total number of patients in the study, around 1 in 5 are anticipated as being eligible to return for follow-up.

Intervention Type
Other

Primary outcome(s)
Glomerular filtration rate (eGFR) using the CKDEpi creatinine formula at baseline and 3 months.

Key secondary outcome(s)
1. Renal function is measured using serum creatinine based eGFR (CKD-Epi), cystatin c based eGFR (CKDEpi) and Iohexol clearance at baseline, 3 months and 1 year post-operatively
2. Occurence of proteinuria or micro-albuminuria measured at baseline, 3 months and 1 year post-operatively

Completion date
01/11/2018

Eligibility

Key inclusion criteria
1. Aged 45 years or over
2. Elective major non-cardiac surgery
3. Anticipated hospital stay of more than 48 hours
4. Prospective written informed patient consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. No fixed address or home location outside of 30km of study centre
3. Purely palliative procedure
4. End Stage Renal Disease (Dialysis, pre-dialysis or conservatively managed CKD Stage 5)
5. Known allergy to iodinated radiological contrast agents
6. Unable to consent/lacks capacity

Date of first enrolment
01/12/2015

Date of final enrolment
01/11/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal London Hospital
Whitechapel Road
Whitechapel
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Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No