

Kidney injury after major surgery

Submission date 05/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/12/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/11/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?
Dr John Prowle, j.prowle@qmul.ac.uk

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Single-centre observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 $>26\mu\text{mol/L}$ within 48h or $\times 1.5$ fold over baseline in over <7 days) or baseline chronic kidney disease (defined by $\text{eGFR} < 60\text{ml/min/1.73m}^2$ 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 measure

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

Secondary outcome measures

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. Occurrence of proteinuria or micro-albuminuria measured at baseline, 3 months and 1 year post-operatively

Overall study start date

01/12/2015

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 1500; UK Sample Size: 1500; Description: We will recruit patients within the UK only.

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**

England

United Kingdom

Study participating centre

The Royal London Hospital

Whitechapel Road

Whitechapel

London

United Kingdom

E1 1BB

Sponsor information**Organisation**

Queen Mary University of London

Sponsor details

10th Floor

Mile End Rd

London

England

United Kingdom

E1 4NS

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Results of this study will be presented at major international meetings in critical care, perioperative medicine and renal medicine and we expect this study to result in several publications in international scientific journals. Publication will follow closure of final follow-up in the study.

Intention to publish date

30/06/2020

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