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Incidence and outcome of perioperative renal failure

Submission date	Recruitment status	[_] Prospectively registered
22/05/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2013	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Though acute kidney injury (AKI) [kidneys suddenly (acute) become unable to do the work expected of them] is extremely common, the knowledge about this disease in the perioperative phase (at or around the time of operation) is very poor. This study aims to understand the interfering factors and predictors of renal function in the perioperative setting (within 48 h postoperatively) after moderate to high-risk surgery in both patients with normal or already preoperatively compromised renal function. Independent predictor for acute kidney injury (AKI) and incidence of AKI in the perioperative setting will be determined. Finally, different types of surgery will be assessed and the relationship between occurrence of AKI and the type of surgery will be assessed. The findings of this study will be used in the improvement and quality program in University Hospital Brussels.

Who can participate?
All patients who underwent a moderate to high-risk surgery in one year will be included in this study.

What does the study involve?
Preoperative and postoperative renal function data, mortality after 30 days after surgery and length of stay in the hospital will be assessed. The association between preoperative patient characteristics and AKI will be assessed. Independent risk factors to develop AKI and on mortality will be determined. Finally, those patients with chronic kidney disease will be analysed separately to determine independent predictors to develop worsening kidney function.

What are the possible benefits and risks of participating?
As this is an observational study, there is no risk.

Where is the study run from?
The study is run from the University Hospital, department of Anesthesiology and Perioperative Medicine in Brussels.

When is the study starting and how long is it expected to run for?
The study started in June 2013 and is expected to last till September 2013.

Who is funding the study?
University Hospital Brussels (Belgium) - Department of Anaesthesiology and Perioperative Medicine

Who is the main contact?
Jan Poelaert, MD, PhD
University Hospital Brussels

Contact information

Type(s)
Scientific

Contact name
Prof Jan Poelaert

Contact details
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1090

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Incidence and outcome of perioperative renal failure after moderate and severe surgery

Study objectives
Retrospectively, incidence of perioperative renal failure in moderate or high risk surgical procedures will be assessed, in addition in those patients with diminished renal function, postoperative renal failure will noted and registered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee University Hospital Brussels, Approval date: 22/12/2011, ref: 2011/282

Study design
Retrospective observational study

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No patient information sheet, as this study is retrospective and observational. The ethics committee waived the use of a patient information sheet.

Health condition(s) or problem(s) studied
Renal failure, postoperative outcome

Interventions
The observational study concerns the occurrence rate of renal failure preoperatively and postoperatively. The purpose is to come to a risk score in our hospital. Therefore we need a large population (we deliberately took one year of patients) and variables such as preoperative status (cardiac, respiratory, renal) as well as the same variables on postoperative day (POD) 1 and 30 day mortality and length of stay in the hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
30 day mortality

Secondary outcome measures
1. Renal function at discharge. The renal function will be assessed according to the RIFLE criteria:
Risk: increase of the serum creatinine x1.5GFR or drop down >25%
Injury: increase of the serum creatinine x2GFR or drop down >50%
Failure: increase of the serum creatininex3 GFR or drop down >75%
Loss: total loss of kidney function for more than 4 weeks
ESDR: complete loss of kidney function, need for dialysis
2. Need for postoperative supportive measures

Overall study start date
01/06/2013

Completion date
01/09/2013

Eligibility

Key inclusion criteria
All patients ≥18 years male/female, who have had in 2010/2011 a moderate to high risk surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The number is not fixed and depends completely on the surgical activity in the investigation year 2010/2011

Key exclusion criteria
1. Absence of moderate or high risk surgery
2. < 18 years and kidney transplant recipients
3. Surgery under local anesthesia
4. Patients in which no serum creatinine determination pre-and postoperative was done
5. Patients who already have preoperative end-stage renal disease (ESRD) according to the RIFLE criteria

Date of first enrolment
01/06/2013

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Belgium

Study participating centre
UZ Brussel
Brussels
Belgium
1090

Sponsor information

Organisation
University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium)

Sponsor details
Department of Anaesthesiology and Perioperative Medicine
Laarbeeklaan 101
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Belgium
1090

Sponsor type
Hospital/treatment centre

Website
http://www.uzbrussel.be

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Brussels (Belgium) - Department of Anaesthesiology and Perioperative Medicine

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration