Diagnostic accuracy of urine biomarkers for acute kidney injury after major surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON42513

Source
ToetsingOnline

Brief title
Urine biomarkers for acute kidney injury

Condition

- Renal disorders (excl nephropathies)
- Gastrointestinal therapeutic procedures

Synonym
acute kidney injury, acute kidney insufficiency, Acute renal failure, acute tubular necrosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute Kidney Injury (AKI), Urine biomarkers

Outcome measures

Primary outcome

The primary objective of the proposed study is to determine which urine biomarkers have sufficient diagnostic accuracy (defined as area under receiver oerating characteristic curve greater than 0.70) for early diagnosis of acute kidney injury (defined as an increase in serum creatinine concentration of more than 26 micromol/L or more than 50% of baseline in the first two postoperative days) in patients undergoing major general surgery. Urine biomarkers to be studied are NGAL, KIM-1 and IL-18; further biomarkers of interest will be identified by systematic review and meta-analysis of the scientific literature.

Secondary outcome

Secondary objectives of the proposed study are:

- To compare the diagnostic accuracy of urine biomarkers for early diagnosis of acute kidney injury.

- To determine the optimal cut-off value and corresponding sensitivity and specificity of the urine biomarkers for acute kidney injury.

- To evaluate the clinical outcome of patients with discordant findings of urine biomarker tests and conventional serum creatinine tests of acute kidney injury.

- To assess whether the diagnostic accuracy of urine biomarkers for early diagnosis of acute kidney injury differs for abdominal surgery and vascular surgery, with the duration of surgery, and with the presence of preoperative

risk factors for AKI (diabetes mellitus, chronic kidney disease [eGFR <60

mL/min], and old age [>70 years]).

- To determine whether urine biomarkers for acute kidney injury and the KDIGO

definition of acute kidney injury are associated with fast renal decline

(defined as eGFR reduction of >4 mL/min/year) at one year after surgery.

- To study the diagnostic accuracy of creatinine clearance in a 15-minute timed

urine collection on arrival at the postoperative recovery unit for early

diagnosis of acute kidney injury.

Study description

Background summary

Acute kidney injury (AKI) is defined as a sudden decrease of renal function with a decline in glomerular filtration rate. AKI encompasses a broad spectrum of different kinds and severity of renal impairment. Possible causes of AKI are ischemia, exposure to nephrotoxic agents, sepsis, volume depletion with reduced renal perfusion, urinary obstruction, glomerulonephritis and acute interstitial nephritis. AKI occurs in 5-15% of all hospital admissions and in 20-45% of patients after major surgery. AKI is associated with short-term adverse events such as increased in-hospital mortality and length of hospital stay. AKI is also associated with long-term mortality and end-stage renal disease, even in patients with initial recovery to baseline serum creatinine concentrations. The severity of AKI is proportional to the short-term mortality risk, but even small increases of creatinine are associated with increased mortality and morbidity. Loss of kidney function can be diagnosed by an increase of serum creatinine concentration and a decrease of urine production. An international consensus definition of acute kidney injury is provided by the Kidney Disease Improving Global Outcomes initiative. Acute kidney injury after major surgery is common and associated with adverse short-term and long-term outcomes. Early detection and treatment of AKI might improve outcomes. The current diagnosis of AKI is based on the gradual accumulation of serum creatinine over the first days after the renal insult, and is therefore not useful for the early detection of AKI. Over the past decade, several groups have identified urine biomarkers for early detection of AKI. These urine biomarkers have mostly been studied in small groups of patients admitted to the intensive care unit or undergoing cardiac surgery and have generally not been replicated to validate

the initial findings.

Study objective

In the current study, we intend to study the diagnostic accuracy of promising urine biomarkers for early detection of acute kidney injury in patients undergoing major general surgery. The study is designed to validate earlier findings in a large group of patients, to extend the use of these biomarkers to general surgery and to select the biomarkers with greatest diagnostic accuracy for clinical use. If the diagnostic accuracy of the biomarkers is sufficiently high, the markers could be used for earlier diagnosis and treatment of AKI.

Study design

This is a predictive diagnostic study. The study group consists of patients undergoing elective major surgery in two hospitals: Maastricht University Medical Center and Zuijderland Ziekenhuis at Heerlen and Geleen. The concentration of urine biomarkers of acute kidney injury and level of serum creatinine will be measured on arrival at the postoperative recovery unit. In the 48 hours after start of surgery, changes in serum creatinine concentrations from baseline will be recorded to establish the gold standard definition of acute kidney injury. The diagnostic accuracy of the biomarkers for early detection of acute kidney injury is assessed as the area under the receiver operating characteristic curves. Long-term decline of renal function will be measured at one year after surgery.

Intervention

The patient will have two extra blood sample collections as intervention.

Study burden and risks

Patients will be exposed to the negligible additional risk of one or two venepunctures (5mL of blood). The timed urine collection and venepuncture on arrival at the postoperative recovery unit will take 15 minutes of time. The venepuncture at 10 to 14 months after surgery will take approximately 15 minutes of time (excluding traveling time). Patients will not experience direct benefits from participating in this study. However, identification of accurate early biomarkers of acute kidney injury may improve treatment of this condition for future patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients of 18 years or older.
Patients who undergo elective major general surgery, including the following operations: open aortic reconstruction, major limb amputation [i.e. transfemoral or transtibial amputations, excluding foot amputations], lower limb bypass surgery, colorectal resection, major liver resection [resection of more than one liver segment], pancreatectomy, oesophagectomy and gastrectomy.

Exclusion criteria

Patients with end-stage renal disease (defined as baseline eGFR *15 mL/min).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	131
Type:	Actual

Ethics review

Approved WMO

Date:	04-11-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52750.068.15

Study results

Date completed: 19-02-2019

Actual enrolment: 11

Summary results
Trial ended prematurely