the IMPact of Aorto-iliac Calcifications prior to kidney Transplantation

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

Summary

ID

NL-OMON45996

Source
ToetsingOnline

Brief title
IMPACT study

Condition

- Renal disorders (excl nephropathies)
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Aorto-iliac calcifications, aorto-iliac vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Kidney transplantation, Pre-operative imaging, Vascular disease

Outcome measures

Primary outcome

Our primary outcome is the correlation between calcification score and kidney function 1-year post-transplantation as measured with the estimated Glomerular Filtration Rate (eGFR) using the Chronic Kidney Disease Epidemiology Collaboration formula (CKD-EPI). Our secondary outcomes are (death-censored) graft survival, patient survival, cardiovascular event-free survival, surgical complications and operation complexity (scored by the transplant surgeon and as measured with operation duration). The primary outcome of the sub-study is change in Fried frailty index and SPPB score 6 months post-transplantation.

Secondary outcome

1. (death-censored) Graft survival at 1 year and 3 years

2. Cardiovascular event-free survival at 1 year and 3 years

3. Patient survival at 1 year and 3 years

4. Incidence of complications after surgery

5. Operation complexity

6. Change in Fried frailty index and SPPB score post-transplantation

Study description

Background summary

The constantly increasing number of aorto-iliac lesions in patients with end-stage renal disease (ESRD) seems to be the result of three main factors:

increased recipient age, frequent atherosclerosis accompanying with end-stage renal disease and commonly present metabolic syndrome (diabetes, hypertension and hypercholesterolemia). These arterial calcifications of the aorta and iliac vessels are a relative contra-indication for kidney transplantation due to possible surgical complexity and cardiovascular comorbidity. The impact of aorto-iliac vascular disease on kidney function, graft survival, surgical complexity and surgical complications remains poorly explored, as well as the most suitable diagnostic imaging to classify the severity of aorto-iliac calcifications.

Frailty is an important topic in kidney transplant recipients who suffer from aorto-iliac vascular disease due to high prevalence of risk factors associated with frailty such as increased age and hemodialysis treatment. Frailty can be measured using Fried frailty index, but it is shown that it can also be measured by lower extremity function using the validated Short Physical Performance Battery score (SPPB). Low SPPB has shown to be an independent risk factor for mortality after kidney transplantation. Prior studies show that Fried frailty index significantly improves after kidney transplantation. It is unknown whether low SPPB score pre-transplantation can be restored after kidney transplantation.

Study objective

The objectives of our study are (1) to evaluate the correlation between aorto-iliac calcification score and kidney function; (2) to investigate the impact of aorto-iliac calcification on graft survival, patient survival and cardiovascular event-free survival; (3) to investigate the impact of aorto-iliac calcification on surgical complexity and surgical complications; (4) to determine predictors in patient demographics and physical examination for significant aorto-iliac vascular disease.
Our sub-study, focusing on frailty in kidney transplant recipients as measured with Fried frailty index and SPPB score, aims to investigate the influence of kidney transplantation on Fried frailty index and SPPB score measured 6 months post-transplantation.

Study design

Prospective, single-center, cohort study

Study burden and risks

The burden for the patient is a pre-transplantation, non-contrast enhanced abdominal CT-scan which is performed at the day the patient is admitted to the hospital. This non-contrast enhanced CT-scan is for research only and is therefore not viewed by the transplant surgeon before surgery. Some patients already require pre-transplantation imaging because of several comorbidities

associated with a higher risk of aorto-iliac calcification. This decision is made at the outpatient clinic of transplant surgery and the CT-scan is then performed after this appointment instead of at the admission day. An abdominal CT-scan can increase the risk of developing cancer at higher age. However, this risk is very small when added to the actual life-time risk of developing cancer (lifetime risk: 1/5, added risk of one abdominal CT-scan: 1/2000).

Fried Frailty score and SPPB score will also be measured at the admission day. These tests take approximately 30 minutes and consist of questions about self-experienced health-related problems and an investigation of the gait speed and balance with five chair-stands test. Post-transplantation Fried frailty index and SPPB score will be measured 6 months post-transplantation. This appointment will be planned prior to/after a regular appointment in the hospital. The measurement of Fried frailty index and SPPB score together takes approximately 30 minutes to complete. Due to logistic reasons, only patients with a living kidney donor or a deceased donor who are admitted during working hours are asked to participate in this sub-study.

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

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- The patient is mentally competent
- The patient is suffering from end-stage renal disease stage IV/V.
- The patient is eligible for kidney transplantation as decided at the outpatient clinic of transplant surgery.
- The age of the patient is >=50 years, or age >=30 years with at least one of the following risk factors: diabetes mellitus, >=1 year of hemodialysis, ethnicity from South-Asia, smoking history of at least 10 packyears, history of peripheral arterial disease, ischemic heart disease or a cerebrovascular accident.
- The patient has given written informed consent to participate in this study.

Exclusion criteria

The following patients are excluded from our study:
- Patients receiving an orthotopic kidney transplantation
- Patients receiving a combined kidney-liver transplantation
- Patients without cardiac clearance to be eligible for kidney transplantation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2018
Enrollment:	141
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL66269.078.18