The assessment of microvascular alterations in renal transplant recipients with and without rejection

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Assessment of microvascular alterations using orthogonal spectral polarization and correlate this with markers for endothelial cell dysfunction, fibrosis and histology in patients with renal function impairment who will undergo renal biopsy and...

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

Summary

ID

NL-OMON33397

Source
ToetsingOnline

Brief title
OPS-1

Condition

- Renal disorders (excl nephropathies)

Synonym
chronische allograft nefropathie, rejection

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: afdeling nierziekten

Intervention

Keyword: microvascular alterations, rejection, renal transplantation

Outcome measures

Primary outcome

1. Non- invasive assessment of microvascular structure using OPS in patients

with and without rejection

Secondary outcome

1. Correlation of microvascular alterations and markers for endothelial

dysfunction, fibrosis and histology

2. Correlation of microvascular alterations and renal function

3. Correlation of microvascular alterations and graft survival

Study description

Background summary

Renal transplantation is the preferred treatment for end-stage kidney failure as it delivers superior patient survival and quality of life compared with dialysis. There have been significant improvements in rates of renal transplant rejection over the last two decades, giving 1-year graft survival rates of over 95%. However this reduction in rejection has not translated into improvements in long-term graft survival. Chronic allograft nephropathy (CAN) and rejection are the most common cause of late transplant failure. In the pathogenesis of CAN and rejection irreversible injury and loss of peritubular capillaries (PTCs) play an important role in the development of graft function deterioration and progressive interstitial fibrosis. The microvasculature of transplanted organs plays an important role in post-transplant graft failure, because of the interaction between inflammatory cells with the microvascular endothelial cell lining during ischemia-reperfusion injury and graft rejection. Since microvasculature endothelial cell injury is associated with graft dysfunction, tubulointerstitial injury and renal fibrosis, measurements enabling early recognition of factors contributing to graft failure may improve outcomes after kidney transplantation. Studies using OPS during kidney and liver transplantation, demonstrated early microvascular changes following

ischemia-reperfusion injury and rejection and a correlation with clinical markers. This indicates a possible therapeutic implication of OPS imaging to predict microvascular alterations in organ transplantation which represents major determinants of graft dysfunction and destruction

Study objective

Assessment of microvascular alterations using orthogonal spectral polarization and correlate this with markers for endothelial cell dysfunction, fibrosis and histology in patients with renal function impairment who will undergo renal biopsy and compare patients with and without rejection/ CAN .

Study design

The study is designed as a prospective observational study. Patients will be included if the have renal impairment after transplantation and had a biopsy for clinical reason with the suspicion of rejection/ CAN. As a control we will include patients with stable renal function after transplantation and healthy controls to compare the OPS measurement en the markers for fibrosis and endothelial dysfunction.

Study burden and risks

Study visits for the renal transplant patients will be planned at outpatient follow-up controls. The visits will take 1hour extra for the OPS measurement. For the healthy controls the visits will take 1,5 hour extra for the OPS measurement, blood and urine samples.

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

Inclusion criteria for renal transplant patients:
1. Age: 18 -70 years
2. Female or male
3. Kidney transplantation(living and cadaveric)
4. Patients who will undergo renal biopsy because of renal function impairment
5. Patients must be able to adhere to the study visit schedule and protocol requirements.
6. Patients must be able to give informed consent and the consent must be obtained prior to any study procedure.;Inclusion criteria for healthy controls:
1. Age: 18-70
2. Female or male

Exclusion criteria

Exclusion criteria for renal transplant patients:
1. Double organ transplantation
2. Patients with evidence of active infection or abcesses.
3. Patients suffering from hepatic failure.
4. Patients suffering from an active autoimmune disease
5. Malignancy (including lymphoproliferative disease) within the past 2-5 years (except for squamous or basal cell carcinoma of the skin that has been treated with no evidence of recurrence)
6. Patients who currently have an active opportunistic infection (e.g., herpes zoster [shingles], cytomegalovirus (CMV), Pneumocystis carinii (PCP), aspergillosis, histoplasmosis, or mycobacteria other than TB)
7. Patients with epilepsy;Exclusion criteria for healthy controls:
1. Smoking (within 1 year prior to screening)
2. History of cardiovascular disease

3. History of malignancy
4. Use of any investigational agent in the last 30 days
5. History of chronic inflammatory disease
6. History of chronic skin diseases
7. History of diabetes mellitus
8. History of alcohol or drug abuse within the last 5 years
9. Hypertension

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-02-2010
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL29142.058.09