Assessment of chronic renal allograft dysfunction with MRI: a pilot study

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To investigate whether it is possible to indicate (focal) IF/TA lesions in renal allografts with MRI and compare these findings to the extent of IF/TA in the kidney biopsy that has been taken previously according to current clinical guidelines.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON47430

Source
ToetsingOnline

Brief title
ACRADYS

Condition

- Nephropathies

Synonym
chronic allograft dysfunction 'interstitial fibrosis and tubular atrophy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chronic allograft dysfunction, interstitial fibrosis and tubular atrophy, kidney transplantation, MRI

Outcome measures

Primary outcome

The main endpoint will be the degree of functional allograft damage.

Differences between values of various MRI parameters (see *5.2 Study Procedures*) obtained in transplantation patients with and without chronic allograft dysfunction on the one hand, and between transplantation patients and healthy (control) volunteers on the other hand, will be analyzed.

Secondary outcome

The secondary endpoint will be the degree of structural allograft damage. This degree will be determined by analyzing the correlation between the best parameter (or combination of parameters) and the degree of IF/TA that was diagnosed in patients included in group A.

Reproducibility of the scan protocol in patients.

Study description

Background summary

A major group of kidney transplantation patients suffers from chronic allograft dysfunction (CAD) within ten years after transplantation. Several conditions can cause CAD (e.g. chronic immunologic response, BK-virus, drug toxicity). Currently, histologic biopsy is the gold standard for diagnosing allograft damage interstitial fibrosis and tubular atrophy (IF/TA) due to CAD. The lesions that become visible in renal biopsies are referred to as *interstitial fibrosis and tubular atrophy* (IF/TA). However, obtaining renal tissue for histology is associated with several disadvantages, including sampling error (resulting in incorrect disease management) and allograft bleeding or

infection. In addition, delayed diagnosis of CAD may lead to allograft loss, and since there is a substantial shortage of organ donors, prolonged allograft survival is of great importance. In conclusion, there is an unmet need for additional diagnostic tools that can be of supportive value in the diagnostic process of CAD. For this, we would like to use MRI (Magnetic resonance imaging) as a novel diagnostic tool to visualize areas of IF/TA in CAD. To our knowledge, a comparison between findings on MRI-images and the degree of IF/TA in the kidney biopsy has not been studied before.

Study objective

To investigate whether it is possible to indicate (focal) IF/TA lesions in renal allografts with MRI and compare these findings to the extent of IF/TA in the kidney biopsy that has been taken previously according to current clinical guidelines.

Study design

Pilot study in 50 volunteers.

Study burden and risks

There are no known risks or adverse effects to MRI, beside dizziness and claustrophobia. The burden for subjects is relatively low in this study, and no contrast is needed. A risk for subjects may be the finding of an unexpected abnormality. When an unexpected abnormality is found, the volunteer and their general practitioner will be informed . In case of a patient their treating specialist will be informed. Because the studied MRI method is no standardized practice, the nature of the abnormality cannot be established with any certainty. To inform the volunteer or patient and their physicians, a letter will be written to explain the finding and to suggest the needed follow up.

There are no direct benefits for the subject. The aim of this study is to develop a new diagnostic tool for renal allograft assessment that is more accurate in an early stage of disease and less invasive than the current gold standard. Therefore addition of renal MRI scanning to existing diagnostic tools can be an improvement for diagnosis of CAD.

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

Group A (n=15):
Patients have undergone at least one kidney transplantation procedure;Patients are 18 year or older;Patients are currently suspect for CAD at the time of inclusion (CAD is defined as a clinical diagnosis characterized by deterioration of kidney function in any way (e.g. increase in SCr, new proteinuria) that demands further diagnostic evaluation; Kidney biopsy is performed according to the existing guidelines for clinical practice just prior to or shortly after the MRI-scan has been performed (time in between the events < 2 weeks) ;Time between NTx and inclusion must be at least 6 months,Patients volunteer to participate and are capable and prepared to sign an informed consent.;Group B (n=20):
Volunteers have undergone at least one kidney transplantation procedure; Volunteers are 18 year or older; volunteers have a well-functioning allograft and are not showing any clinical signs of allograft dysfunction; Time between NTx and inclusion is at least 3 months; Volunteers are capable and prepared to sign an informed consent;Group C1 (n=15 - x):
Volunteers have donated a kidney to someone that is included in group A or B; Volunteers are 18 year or older; Volunteers are not altruistic kidney donor; Volunteers are not diagnosed with any renal disease; Volunteers are prepared to give a blood sample for analysis of the SCr; Volunteers are capable and prepared to sign an informed consent.;Group C2 (n=x):
Volunteers are 18 year or older; Volunteers are not diagnosed with any renal disease; Volunteers are prepared to give a blood sample for analysis of the SCr; Volunteers are

capable and prepared to sign an informed consent; Volunteers can be sex- and age matched within a range of 5 years to patients in group A/B1 (who are not already matched to their donor). Part of the volunteer data will consist of data from volunteers who are already scanned for another study (ReMARK, METC NL45144.041.13, 13/402) under the same conditions with the same scan protocol.

Exclusion criteria

Volunteers with contra-indications for MRI (like a pacemaker, an internal prosthesis or claustrophobia); Refusal of volunteers to be informed of chance findings possibly relevant to their health; Pregnancy.

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:	Recruitment stopped
Start date (anticipated):	14-12-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	21-09-2015
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26023
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL53885.041.15
OMON	NL-OMON26023