Assessment of chronic dysfunction of kidney transplants with MRI

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26023

Source
NTR

Brief title
ACRADYS

Health condition

kidney transplantation
MRI
chronic renal allograft dysfucntion
niertransplantatie
chronisch nierfalen van transplantaatnieren

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Correlation of MR markers with interstitial fibrosis / tubular atrophy lesions on biopsy

Secondary outcome

Clinical markers of renal function

Differences in MR markers between groups

Study description

Background summary

The aim of the study is to detect (focal) interstitial fibrosis or rubular atrophy lesions in kidney allografts using MRI. Three groups of subjects are included: subjects >3 months after transplantation with stable graft function who preferably do have a routine kidney biopsy; subjects >6 months after transplantation suspect for chronic allograft dysfunction with an indication biopsy; healthy volunteers without kidney disease as comparison. All participants get a one-hour MRI scan to measure several functional parameters of kidney function. Correlations with biopsy and differences between groups will be investigated.

Study objective

To investigate whether it is possible to indicate (focal) interstitial fibrosis / tubular atrophy lesions in kidney allografts with MRI and compare these findings to the extent of interstitial fibrosis / tubular atrophy in the kidney biopsy that will be taken according to current clinical practice.

Study design

Single timepoint >3 months post transplantation

Intervention

-

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• Patients have undergone at least one kidney transplantation procedure.

• Patients are 18 year or older.

• 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 between NTx and inclusion must be at least 3 months for patients with well functioning transplants and 6 months for patients with suspected chronic allograft dysfunction

Also healthy volunteers are included as comparison.

Exclusion criteria

• Subjects with contra-indications for MRI (like a pacemaker, an internal prosthesis or claustrophobia).

• Refusal of subjects to be informed of chance findings possibly relevant to their health.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	14-12-2017
Enrollment:	50
Type:	Unknown

Ethics review

Positive opinion
Date: 23-11-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47430
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7412
NTR-old	NTR7637
CCMO	NL53885.041.15
OMON	NL-OMON47430

Study results

Summary results
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