Studying Cognitive Outcome of Renal Transplantation with a Kidney of a Live Donor

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We will investigate the changes in mental performance using a validated computerized test battery of neuropschychological tests just before and one year after transplantation. Using visual and auditory information stimuli, these tests measure speed...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON41620

Source
ToetsingOnline

Brief title
SCORE

Condition

- Cognitive and attention disorders and disturbances

Synonym
executive tasks and/or information processing, functioning of memory, language

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Fonds Niertransplantatie

Intervention

Keyword: cognitive impairment, immunosuppression, renal transplantation

Outcome measures

Primary outcome

The change in mental performance in kidney recipients at twelve months after transplantation compared to pre-transplantation.

Secondary outcome

o The change in mental performance in kidney recipients at twelve months after transplantation compared to the change in mental performance in kidney donors.

o Changes in cortical, hippocampal, temporal atrophy and global cerebral atrophy, using both visual rating scales as well as volumetric analyses.

o Changes in white matter lesions using both visual rating scales as well as volumetric analyses.

o Presence of microinfarctions and areas with microbleeding at baseline and occurrence of new lesions during followup.

o Change in cerebral blood flow as measured by arterial spin labelling.

Study description

Background summary

Cognitive impairment is common in Chronic Kidney Disease (CKD) and is associated with decreased quality of life, higher morbidity and mortality, decreased medical adherence and increased medical costs. Early recognition of impaired cognitive function is important because it enables health care professionals to implement measures to improve coping and reduce deterioration. This will improve quality of life, increase medical adherence to the often complicated medication schemes and reduce health care costs.

Previously, it has been shown that in middle age, end-stage-renal-disease (ESRD) patients, cognitive performance improves after renal transplantation. However, no data exist whether this improvement in cognitive performance is reflected by normalization of the abnormalities seen on MRI in chronic kidney disease.

Study objective

We will investigate the changes in mental performance using a validated computerized test battery of neuropschychological tests just before and one year after transplantation. Using visual and auditory information stimuli, these tests measure speed, stability and accuracy of various basic neuropsychological processes underlying neurocognitive function, i.e. sustained attention and executive functions such as working memory, inhibitory control and cognitive flexibility. In addition, psychomotor functions will be performed, as well as a POMS (profile of mood states) assessment and a verbal fluency test.

We will compare the results of neuropsychological testing with neuro-imaging. MRI scanning will be performed pre- and posttransplantation to assess white matter lesions, brain atrophy, cerebral perfusion and specific intracerebral lesions that are associated with neuropsychological deficits. To our knowledge, there are no prospective studies in renal transplant patients that use both neuropsychological testing and MRI scanning as tools to evaluate cognitive function.

Study design

The design of the study is a prospective observational cohort study

Study burden and risks

negligible

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients undergoing a scheduled renal transplantation with a live kidney donor before having started dialysis or within one year after starting dialysis and their donors.
* Sufficient visual and hearing acuity
* Dutch or English language fluency
* Willingness to give informed consent
* ABO compatible

Exclusion criteria

* Pre-existing documented cognitive impairment
* A history of psychiatric illness
* Use of psychoactive substances
* A history of cerebrovascular disease (either transitory ischaemic attack or cerebrovascular accident)
* Brain injury
* Epilepsy
* Acute or chronic infections
* Malignancy
* Unstable coronary vascular disease
* Uncontrolled hypertension
* Liver disease or other metabolic disease leading to encephalopathy
* Diabetes mellitus
* Uncorrected anemia (Hb <7,0 mmol/L)

* MR contraindications, including implanted active devices or objects (e.g. cardiac pacemaker, implantable defibrillator, medication pump, intracranial aneurysm clips, cochlear implant and other implants), metal splinters near sensitive organs (e.g. eye, brain or lungs) or claustrophobia.
* Any condition that can be expected to interfere with complete follow-up
* Patients participating in group 1 of the ALLEGRO trial
* HLA-identical family transplantations

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):	30-10-2013
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL41987.018.13