Cognitive function and uremic toxins in patients with severe renal failure: a pilot study

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Primary Objective: - to determine cognitive impairment in patients with severe renal failureSecondary Objective(s): - to determine to what extent this impairment improves after a kidney transplantation - to evaluate changes in uremic toxins after...

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

Summary

ID

NL-OMON42335

Source
ToetsingOnline

Brief title
Cognitive function and uremic toxins

Condition

- Cognitive and attention disorders and disturbances
- Renal disorders (excl nephropathies)

Synonym
cognitive disorders, Cognitive impairment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognition, Kidney transplantation, Severe renal failure, Uremic toxins

Outcome measures

Primary outcome

1. Differences in cognitive test performances with respect to validated

referenced values in the 3 different study groeps.

Secondary outcome

1. The differences in test scores between the 3 consecutive neuropsychological

assessments.

2. The difference in uremic toxin concentration before and after kidney

transplantation.

Study description

Background summary

A vast proportion of patients on dialysis still suffer from the uremic syndrome despite achieving their dialysis targets. The uremic syndrome can be defined as a modification of biochemical or physiologic functions as a result of the accumulation of a large number of compounds due to a deficient renal clearance. As a consequence uremic complaints in this population (i.e. anorexia, inflammation, and cardiovascular diseases) are not uncommon. In addition, we noticed the presence of cognitive disorders in this group of patients. This is supported by literature demonstrating that dialysis patients present with mild to moderate impairment in multiple domains of cognitive function. On the contrary, transplant patients show normal or near normal cognitive function. We hypothesize that uremic toxins play a major role in the development of cognitive impairment, and therefore, we expect that decreasing uremic toxin levels will improve cognitive function.
The aim of this study is to assess the degree of cognitive impairment in dialysis patients in comparison with non-dialyzed patients with renal insufficiency and to determine to what extent this impairment improves after a

kidney transplantation. In addition, we want to investigate which (group of) uremic toxins are associated with developing cognitive impairment.
If the contributing uremic toxins can be determined, it is conceivable that modifying the uremic toxins levels, i.e. by dietary adaptations or probiotics, could improve cognitive function in patients on dialysis.

Study objective

Primary Objective:
- to determine cognitive impairment in patients with severe renal failure

Secondary Objective(s):
- to determine to what extent this impairment improves after a kidney transplantation
- to evaluate changes in uremic toxins after transplantation

Study design

This is an observational cohort and pilot study in which several neuropsychological tests, examining the main cognitive domains (intelligence, memory, attention and concentration, executive functions) and suboptimal performance (i.e. malingering), will be performed in three different groups of patients with severe renal insufficiency. In addition to the neuropsychological tests, four questionnaires will be used to assess subjective cognitive complaints, quality of life, mood, and the degree of fatigue.
In addition, blood samples will be drawn from the patients in order to determine the presence of uremic toxins.

The neuropsychological tests and questionnaires will be administered by a trained neuropsychologist. The blood samples will be taken by trained nurses.

Study burden and risks

Participants will be subjected to a neuropsychological assessment 3 times. Each assessment will take 1,5 hour and will be administered during either a regular outpatient clinic visit or hospital admission. In addition, participants will be asked to fill in four questionnaires that will take about 15 minutes to complete. Finally, an extra sample of blood will be drawn during regular blood taking moments.

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

- Patients with CKD and receiving a living kidney transplantation within 4-6 weeks
- Patient with CKD, dialysis dependent
- Patient with low eGFR (eGFR < 30 ml/min) not on dialysis
- Age >= 18 years old
- Written informed consent for study

Exclusion criteria

- Any other (neurological) disorder which may impact cognitive function
- Evident cerebrovascular diseases
- Presence of acute or chronic psychosis, evident depression, severe learning disabilities
- Major visual or hearing impairment
- Not fluent in written and spoken Dutch
- Inability to provide informed consent

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	13-08-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL54109.091.15