Cognitive Decline in Older Patients with End stage Renal Disease

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Knowledge on the magnitude of the decline and the pathophysiological mechanism can eventually help us topostulate an algorithm for well-balanced decision making in treatment strategies in the elderly CKD patients.This knowledge will be firmly...

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

Summary

ID

NL-OMON44778

Source
ToetsingOnline

Brief title
COPE

Condition

- Renal disorders (excl nephropathies)

Synonym
Kidney Failure; cognition

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cognitive impairment, ESRD, Nephrology, Older Patients

Outcome measures

Primary outcome

Our primary analysis will be to calculate the mean change in MMSE score and cognitive test battery (Stroop, Letter Digit Coding Test and Picture Learning, Immediate and Delayed) after initiation of RRT.

To determine whether this change in cognitive function is attributable to the initiation of RRT, we will compare these change to

1) change in MMSE score and cognitive and functional test battery in those older patients who did not initiate RRT in two consecutive years (n=200),

2) change in MMSE score and cognitive and functional test battery in the individuals who did initiate RRT in two consecutive years prior to start of RRT.

3) the association between the change in MMSE score and cognitive and functional test battery after initiation of RRT with various parameters of brain structure (measures of vascular cognitive impairment) or perfusion (measures of auto-regulation) at baseline.

Secondary outcome

Our secondary analysis will be:

1) to evaluate the correlation between the results of CGA and cognitive test battery and cardiovascular markers and disease, metabolic parameters, and (the rate of decline) of eGFR.

2) Correlation between outcome of CGA and the impact of disease on quality of

life.

Study description

Background summary

Patients with End Stage Renal Disease (ESRD) who initiate haemodialysis are at risk for cognitive decline,
but the magnitude of the decline and the pathophysiological mechanism is largely unknown. There is a rising
influx of elderly patients with ESRD starting with renal hemodialysis in the last decade and their number will
continue to increase. Both cognitive impairment and higher age are risk factors for poor outcome in patients
on hemodialysis. Furthermore, such cognitive function should be assessed in the context of overall
functioning, which in older patients is usually assessed using a comprehensive geriatric assessment (CGA).
Overall changes in co-morbidity, frailty and functioning may contribute to cognitive decline and should
therefore be assessed in parallel.
Brain perfusion plays an important role in cognitive function. Several processes which are highly prevalent
among older patients with ESRD, such as chronic hypertension, stroke and atherosclerosis, influence
cerebral auto-regulation. It is therefore conceivable that there is a concomitant disturbance of cerebral autoregulation,
resulting in disturbances in brain perfusion and structural changes, finally leading to cognitive
decline.
We hypothesize that auto-regulation of brain perfusion is disturbed in older patients with ESRD and that
initiation of hemodialysis results in decreased brain perfusion by disturbing hemodynamics. We also
hypothesize that this dysregulation contributes to the cognitive decline in these patients.
The overall aim of the present project is therefore to quantify the rate of cognitive decline in
in older patients with end stage renal disease who initiate hemodialysis and assess whether the rate
of cognitive decline can be explained by disturbances of brain perfusion.
In this prospective cohort study we will include and follow older (65-plus years) patients with ESRD in predialysis
outpatient clinics. We will administer a CGA to quantify the cognitive function

using a standardized
cognitive test battery and overall functioning as well as MRI scans of the
brain including brain structure and
perfusion. All participants will be followed annually, including 6 months after
initiation of hemodialysis. We
target to include 100 new hemodialysis patients and assess 1) the rate of
cognitive decline after initiation of
hemodialysis, 2) the effect of hemodialysis on brain perfusion, and 3) the
association between cognitive
decline and initial disturbances in brain structure or perfusion.

Study objective

Knowledge on the magnitude of the decline and the pathophysiological mechanism
can eventually help us to
postulate an algorithm for well-balanced decision making in treatment
strategies in the elderly CKD patients.
This knowledge will be firmly embedded and implemented in our new out-patient
clinic for older patients with
ESRD.

Study design

observational, multicenter

Study burden and risks

limited burden involved
1. totale time investment is limited (regular out-patient visits
2. No risks (observational investigation)

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

> 65 years of age with eGFR < 20 ml/min during the past 6 months.

Exclusion criteria

Illiterat
foreign language
Unable to give informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46389.058.13