Treatment transitions in uremia: A survey on the effects of dialysis on cardiovascular and nutritional state, and physical activity

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

Summary

ID

NL-OMON39790

Source
ToetsingOnline

Brief title
Transitions in uremia

Condition

- Nephropathies

Synonym
dialysis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Fresenius FMC,via een unrestricted grant van Fresenius MC. Deze firma is geen opdrachtgever en heeft geen invloed op de uitvoering en verwerking van het onderzoek.

Intervention

Keyword: dialysis, overhydration, physical activity, pulse wave analysis

Outcome measures

Primary outcome

overhydration (bioimpedance)

pulse wave analysis

body composition (bioimpedance)

physical activity (Sensewear armband)

Secondary outcome

capillary microscopy

handgrip strength

laboratory parameters

skin autofluorescence

Study description

Background summary

In the life of patients with end-stage renal disease, the start of dialysis is a major life event. Many dialysis patients suffer from cardiovascular disease and malnutrition, and their physical activity levels are low. It is difficult to unravel the effects of uremia on these parameters of those from dialysis treatment. The aim of this study is to assess the effects of dialysis on cardiovascular and nutritional parameters, as well as physical activity levels. This study may be of relevance given the uncertainties of the optimal time point to start dialysis.

Study objective

The main of objectives are to study the effect of the start of dialysis treatment (hemodialysis and peritoneal transplantation), on selected cardiovascular, nutritional parameters as well as physical activity. Secondly, a differentiation will be made between patients who start treatment with peritoneal dialysis or hemodialysis.

Study design

This is a longitudinal observational study, with a follow-up duration of 12-15 months. Measurements will be performed at 6 different point in time. Except for blood sampling, this is a non-interventional study with non-invasive measurements. Blood sampling will as much as possible co-incide with regular sampling moments. The interventions which are studied (dialysis, transplantation) are part of usual patient care.

Study burden and risks

in this study, only non-invasive techniques which pose a minimal burden to the patient. Blood sampling will coincide as much as possible with regular blood takings for clinical purposes. The study will not have direct benefit for the participants. The study can only be performed with this specific patient group.

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

Age> or equal to 18 years
Ability to provide written informed consent
Voorgenomen start van dialysebehandeling (patienten)

Exclusion criteria

An acute start of dialysis treatment, i.e. patients who did not visit the pre-dialysis out-patient clinic on forehand. Reason for exclusion is the fact that in these patients often acute and intercurrent diseases are present, which may significantly interfere with the measurements.
Inability to provide informed consent
Active symptomatic coronary artery disease NYHA III or higher, or cardiac failure NYHA III or higher
Active malignancies
Active infections;Hypertension (blood pressure higher than 170 mmHg systolic or 100 mmHg diastolic at the time of screening) [controls]
Diabetes mellitus [controls]

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-11-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-11-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-02-2013

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-11-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33129.068.10