Inflammation, overhydration, and silent coronary ischemia in dialysis patients: a longitudinal cohort study

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Aim of the present study is to test the hypothesis tha during inflammatory episodes there is a decline in lean body and fat mass and that this results in an increase in extracellular volume in dialysis patients because dry weight is not or…

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

Summary

ID

NL-OMON29707

Source
ToetsingOnline

Brief title
Inflammation, overhydration, and coronary ischemia in dialysis patients

Condition

- Renal disorders (excl nephropathies)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Coronary ischemia, Dialysis, Inflammation, Overhydration

Outcome measures

Primary outcome

The parameters of the study are a bioimpedance measurement, a handgrip test, a questionnaire, an inspection of the fat and muscle mass and blood samples for CRP and Troponin T levels.

Secondary outcome

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Study description

Background summary

Overhydration (an excess of body water) is commonly present in dialysis patients.
Overhydration may lead to silent myocardial ischemia, although this has not been formally studied. Recent studies found a relation between extracellular volume and C-reactive protein levels, a marker of inflammation. The first explanation is that overhydration itself may induce inflammation. An alternative explanation is loss of lean body mass in the inflammatory state which leads to progressive overhydration if not appropriately detected and treated.

Study objective

Aim of the present study is to test the hypothesis tha during inflammatory episodes there is a decline in lean body and fat mass and that this results in an increase in extracellular volume in dialysis patients because dry weight is not or insufficiently adjusted.
The second hypothesis that is to be tested is that overhydration is related to subclinical changes in Troponin T as a marker of silent coronary ischemia.

Study design

This is a longitudinal cohort study with a follow-up period of 6 months.

Measurements will be performed every 2 months and also when a patient is admitted to the hospital for a clinical event or for surgery. Three days after admission of the patient measurements will be performed and this will be repeated every three days with a maximum of two. In case of recurrent hospitalization, patients will not more than two hospitalization episodes be assessed.

Study burden and risks

This is a non-invasive study with no risks for patinets. The extra amount of blood taken from the patient will be no more than 60 milliltres the entire study.

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

Treatment with hemodialysis or peritoneal dialysis

Exclusion criteria

pacemaker
onmogelijkheid om informed consent te geven

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2006
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	29-05-2006
Application type:	First submission
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	NL12014.068.06