Hemodialysis-associated left ventricular dysfunction: identification of dialysis-induced triggers, prevalence and prognostic impact.

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1. To establish the prevalence and prognostic impact of HD-associated LV dysfunction; 2. To identify (clues to) mechanisms/ pathways that are pathophysiologically involved in HD-associated LV function.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33776

Source
ToetsingOnline

Brief title
HD-associated LV dysfunction

Condition

- Cardiac disorders, signs and symptoms NEC
- Urethral disorders (excl calculi)

Synonym
Left ventricular dysfunction; left ventricular wall motion abnormality

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac, dysfunction, hemodialysis, hypotension

Outcome measures

Primary outcome

The prevalence of HD-associated LV dysfunction as assessed by pre-, intra-, and post-HD echocardiography.

Secondary outcome

To elucidate the mechanisms/ pathways that are pathophysiologically involved in HD-associated LV dysfunction we will relate its occurrence to pre-HD levels and intra-HD alterations in biomarkers of the inflammatory response (hsCRP, IL-6, pentraxin III), oxidative stress (SOD, MDA, AGEs), bioincompatibility (complement, leukocytes), endothelial dysfunction/ activation (von Willebrand factor), and with autonomic dysfunction (HRV). The choice for these pathways is based on their likely role in both the regulation of MBF and the increased risk of adverse cardiac events. Finally, we will evaluate the outcome of this cohort during a 2-year follow-up and analyse for the prognostic impact of LV dysfunction on predefined cardiovascular events and changes in LV function by repeat echocardiography at 1 year and at 2 years.

Study description

Background summary

Whereas hemodialysis (HD) is life-saving by replacement of renal function, there is data to suggest that adverse effects of the HD procedure as such contribute to the high cardiovascular risk in HD patients. By applying PET scanning in HD patients, we and others demonstrated that HD sessions elicit reductions in myocardial blood flow (MBF), even in the absence of ultrafiltration (UF). Moreover, in some patients the fall in MBF was severe enough to result in reversible left ventricular (LV) systolic dysfunction (hypokinesia/ akinesia) in regions with the greatest fall in MBF, indicative of stunning. In patients with ischemic heart disease, stunning is a strong predictor of a dismal prognosis. Likewise, repetitive HD-associated myocardial ischemia of sufficient intensity to result in LV dysfunction might be a pathogenetic factor in the high cardiovascular morbidity and mortality in HD patients. HD-associated myocardial ischemia may trigger arrhythmias and repetitive ischemia may lead to cumulative LV dysfunction and eventually result in heart failure, a highly prevalent condition in HD patients. The prevalence of HD-associated LV dysfunction in our HD population is unknown but our data and those by others suggest it may occur relatively frequent.

Study objective

1. To establish the prevalence and prognostic impact of HD-associated LV dysfunction;
2. To identify (clues to) mechanisms/ pathways that are pathophysiologically involved in HD-associated LV function.

Study design

Observational cohort study.

Study burden and risks

The study has limited patient burden. No invasive investigations are performed. No extra visits are necessary. During a single - regular - HD session, a total of 4 echocardiographies will be performed immediately before, during, and after HD. At this single HD session, blood sampling will be done before, during and after HD. Blood will be sampled from the arterial line of the HD circuit and no venapunctions are required. During this (single) HD session, a continuous 3-lead ECG-registration will be performed. Skin Auto Fluorescent will be measured before and after HD by the AGE reader. This is a non-invasive technique that measures skin autofluorescence on the ventral site of the lower arm. The procedure takes less than 2 minutes and is not painful.The follow-up echocardiographies at 1 and 2 years are part of the usual, routine, patient care.

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

Adult (age >=18 years old) maintenance hemodialysis patients.

Exclusion criteria

Pre-existing severe (New York Heart Association class IV) left ventricular systolic failure or inadequate echocardiographical windows to obtain images of sufficient quality.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2009
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26298.042.08