Gated 13N-NH3 PET before and during hemodialysis for the assessment of changes in myocardial perfusion, volumes and output of the left ventricle.

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First: to determine the technical and logistical feasibility of measuring changes in myocardial perfusion and left ventricular function with gated 13N-NH3 PET before and during HD.
Second: to compare changes in myocardial perfusion and left...

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

Summary

ID

NL-OMON30270

Source
ToetsingOnline

Brief title
Gated 13N-NH3 PET during HD

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
cardiac perfusion, left ventricular function

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gated 13N-NH3 PET, hemodialysis, left ventricular function, myocardial perfusion

Outcome measures

Primary outcome

The outcome parameters are changes in cardiac output, myocardial contractility, left ventricular ejection fraction, left ventricular diameter, left ventricular end-systolic volume, left ventricular end-diastolic volume, left ventricular myocardial perfusion in ml/min/g and regional wall motions. Data will be analysed quantitatively and displayed in a 17-segment polar map. Each individual session will be evaluated for pre- and post-study body weight, total ultrafiltration volume, blood pressure and the course of relative blood volume (measured non-invasively by an RBV monitor) throughout the study.

Secondary outcome

n.a.

Study description

Background summary

Dialysis induced hypotension is an important complication of the hemodialysis (HD) treatment. Two factors play a crucial role in the aetiology of HD hypotension: 1. A decrease in blood volume during HD. 2. The capacity of the cardiovascular system to respond adequately to this decrease in blood volume. Patients on renal replacement therapy have a variety of cardiac abnormalities. Several studies have shown that cardiac output, and myocardial contractility significantly falls during HD. At present it is not known if this reduction in cardiac output is primarily caused by a reduction in filling pressure of the left ventricle, induced by a decrease in venous return in combination with diastolic dysfunction, or by myocardial ischemia leading to a decrease in

cardiac output through regional wall motion abnormalities. Positron emission tomography (PET) is an advanced imaging technique that allows precise quantification of myocardial perfusion, metabolism and volume and function of the left ventricle.

Study objective

First: to determine the technical and logistical feasibility of measuring changes in myocardial perfusion and left ventricular function with gated 13N-NH3 PET before and during HD. Second: to compare changes in myocardial perfusion and left ventricular function before and during hemodialysis.

Study design

Eight HD patients will be recruited to participate in the study. By applying the protocol first in two HD patients we investigate whether or not it is technically and logistically feasible to evaluate if changes in cardiac behaviour during HD can be detected. If this is not feasible, the study will be terminated. If this is feasible, then in an additional six patients we will compare changes in myocardial perfusion and left ventricular function before and during hemodialysis. Patients will undergo three gated 13N-NH3 PET measurements in order to evaluate if changes in cardiac behaviour during HD can be detected. The first gated 13N-NH3 PET will be performed 25 minutes prior to the start of the HD treatment. Ten minutes after the start of HD, the second scan will be performed. After the 2nd scan, patients will be transferred onto a normal bed since this is more comfortable. The 3rd and last scan will be performed 3 hours and 15 minutes after the start of HD. Since intra-vascular volume depletion is most prominent when one nears the end of the HD treatment, we, therefore, expect to find the largest difference with baseline in the last hour of HD.

Study burden and risks

Patients will have to stay 25 minutes longer in the hospital than usual for a conventional hemodialysis treatment. Two dialysis needles will be inserted in the arterio-venous fistula, however, these needles should also have been inserted without participating in this study. Patients will further undergo: 1) The inconvenience of lying in the PET-camera for 1 hour and 15 minutes for the first 2 scans, and an additional 40 minutes for the final scan. 2) The total amount of radiation from the radiopharmaceuticals leads to a radiation exposure of 3,2 mSv (1200 MegaBecquerel (MBq)) for the whole duration of the study for each participating hemodialysis patient. Each bolus of 13N-NH3 contains 400 MBq.

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

1) Adult (age equal to/above 18) HD patients who have been treated with HD for at least six months. 2) Patients must have an arterio-venous fistula without recirculation established by Transonic flow measurements.

Exclusion criteria

1. The absence of informed consent (see ethical considerations). 2. The need to perform HD with pre-dilution. 3. Recent haemorrhage. 4. Unstable angina pectoris. 5. History of myocardial infarction. 6. Inability to endure a horizontal position for a longer period of time. 7. Arrhythmia. 8. The use of long-acting nitrates. 9. Left ventricular ejection fraction <= 30%. 10. Diabetes Mellitus. 11. Pregnancy or suspicion hereof.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2007
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	13H-NH3

Ethics review

Approved WMO Date:	20-04-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-05-2006
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
EudraCT	EUCTR2006-000867-27-NL
CCMO	NL11063.042.06